

Message

From: Huff, Lisa [Huff.Lisa@epa.gov]
Sent: 7/10/2017 7:11:51 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: RE: briefings on OW actions

Ok Wed. out the door? And presuming you and Peter ? will want to review before the presentation is sent over, right?

Lisa Foersom Huff

Associate Branch Chief
Targeting and Analysis Branch
Standards and Risk Management Division
Office of Groundwater and Drinking Water
U.S. EPA
EPA East Bldg. Rm. 2357 H
202-566-0787

From: Burneson, Eric
Sent: Monday, July 10, 2017 2:25 PM
To: Huff, Lisa <Huff.Lisa@epa.gov>
Subject: RE: briefings on OW actions

Lets target Weds for the materials.

From: Huff, Lisa
Sent: Monday, July 10, 2017 12:58 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: briefings on OW actions

Thanks Eric for the heads up – how far in advance do they need the materials?

Also I see that Caryn included the link for the BBDR report – note that the peer review summary is in a different docket as I noted in my email to you just a bit ago (that's why it took me a bit longer than I expected to send you the link(s) for both documents in 2 separate dockets -0438 and -0439).

Peer review report is in docket ending in -0439 found at <https://www.regulations.gov/document?D=EPA-HQ-OW-2016-0439-0006>

Lisa Foersom Huff

Associate Branch Chief
Targeting and Analysis Branch
Standards and Risk Management Division
Office of Groundwater and Drinking Water
U.S. EPA
EPA East Bldg. Rm. 2357 H
202-566-0787

From: Burneson, Eric
Sent: Monday, July 10, 2017 12:52 PM
To: Huff, Lisa <Huff.Lisa@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>
Cc: Hafez, Ahmed <Hafez.Ahmed@epa.gov>
Subject: FW: briefings on OW actions

FYI looks like this meeting will be happening on Tuesday the 18th at 2:00 and we will need to get materials over in advance.

From: Schwab, Margo EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: Monday, July 10, 2017 12:08 PM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Cc: James H Kim@ **Ex. 6 Personal Privacy (PP)** Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: briefings on OW actions

My preference is for Tuesday

From: Muellerleile, Caryn [mailto:Muellerleile.Caryn@epa.gov]
Sent: Monday, July 10, 2017 11:13 AM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)** >; Schwab, Margo EOP/OMB
Ex. 6 Personal Privacy (PP)
Cc: Kim, Jim H. EOP/OMB <J **Ex. 6 Personal Privacy (PP)** >; Kim, Jim H. EOP/OMB **Ex. 6 Personal Privacy (PP)**
Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: briefings on OW actions

Hello,

Just checking in to see if you have a preference for meeting dates: next Tues 7/18 at 2 p.m. or Wed. 7/19 at 3 p.m.?

Also, the draft BBDR model that EPA released last year and subsequent public comments are all available at:
><https://www.regulations.gov/docket?D=EPA-HQ-OW-2016-0438><.

thank you,
Caryn

Caryn Muellerleile
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1200 Pennsylvania Ave NW (1803A)
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(202) 564-2855
muellerleile.caryn@epa.gov

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: Friday, July 07, 2017 10:44 AM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>
Cc: Nurse, Leanne <Nurse.Leanne@epa.gov>; James H Kim@ **Ex. 6 Personal Privacy (PP)** Schwab,

Margo EOP/OMB <Ex. 6 Personal Privacy (PP)>

Subject: RE: briefings on OW actions

Adding Margo to this chain because I accidentally omitted her from my original email. We'll get back to you as soon.

From: Muellerleile, Caryn [mailto:Muellerleile.Caryn@epa.gov]

Sent: Friday, July 7, 2017 10:09 AM

To: Dorjets, Vlad EOP/OMB <Ex. 6 Personal Privacy (PP)>

Cc: Nurse, Leanne <Nurse.Leanne@epa.gov>; Kim, Jim H. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Kim, Jim H. EOP/OMB <Ex. 6 Personal Privacy (PP)>

Subject: RE: briefings on OW actions

Hello,

Additional update. EPA plans to provide the briefing presentation and draft charge questions prior to the meeting as we did for the first round. We agree that it would be helpful for everyone to have these a few days ahead of time. Below is our proposed agenda:

- Perchlorate BBDR Model Peer Review Outcome
 - Reviewers response to charge
 - EPA's actions on peer review recommendations
- Overview of Revisions to the BBDR Model
- MCLG Approaches
- Next Steps

Alternate suggested dates for the meeting: July 18 from 2-3pm or July 19 from 3-4pm. Let me know if either of these work for you.

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muellerleile.caryn@epa.gov

From: Dorjets, Vlad EOP/OMB <Ex. 6 Personal Privacy (PP)>

Sent: Thursday, July 06, 2017 3:23 PM

To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>

Cc: Nurse, Leanne <Nurse.Leanne@epa.gov>; James H Kim <Ex. 6 Personal Privacy (PP)>

Subject: RE: briefings on OW actions

Caryn,

Thanks for setting up the meeting for Monday. I was getting ready to send out an invitation to interagency reviewers when I realized three things: First, I'm worried that we may be giving Agencies too little time to identify and invite the appropriate people (especially with tomorrow being Friday). Second, even if the right people are able to participate in the call, they won't have much time to review the briefing material. Third, I think there is still some confusion about exactly what material EPA plans to provide in advance of the call and even what the briefing will cover. Can you please let me know whether you plan to provide OMB and reviewers with the draft BBDR model report or the draft MCLG

approach report? We think it would be of great value to allow people to review those reports prior to the call so that they can ask more informed questions. Along, similar lines could you please confirm that EPA plans to discuss the comments it received to the BBDR model and the changes made to the model in addition to the MCLG report?

I think that reviewers need at least several days (if not a week) to review the report(s) so if you can get those to me today to circulate we can set up the briefing for late next week. What do you think? Happy to discuss by phone if you think that's easier.

Vlad

From: Muellerleile, Caryn [<mailto:Muellerleile.Caryn@epa.gov>]
Sent: Wednesday, July 5, 2017 1:47 PM
To: Schwab, Margo EOP/OMB <[Ex. 6 Personal Privacy \(PP\)](#)>; Dorjets, Vlad EOP/OMB
<[Ex. 6 Personal Privacy \(PP\)](#)>
Cc: Nurse, Leanne <Nurse.Leanne@epa.gov>
Subject: RE: briefings on OW actions

Hello,

I'm seeking to set up another meeting day/time with you all and others (DOD, NASA, etc) to discuss EPA's peer review materials for perchlorate. Do any of the following days/times work for you?

Mon. 7/10 from 10-11 or 2-3

Wed. 7/12 from 10-11

Also, would you like to forward EPA's invitation or would you prefer to send me the names of other federal invitees?

thank you,
Caryn

Caryn Muellerleile
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Office of Policy
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(202) 564-2855
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From: Schwab, Margo EOP/OMB <[Ex. 6 Personal Privacy \(PP\)](#)>
Sent: Thursday, June 15, 2017 5:09 PM
To: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy \(PP\)](#)>; Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>
Cc: Nurse, Leanne <Nurse.Leanne@epa.gov>
Subject: RE: briefings on OW actions

The following time works for us. Please send us both an invite with a call in number. Thank you!
6/29/17 (Thurs) 3-4

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 15, 2017 4:11 PM

To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>

Cc: Nurse, Leanne <Nurse.Leanne@epa.gov>; Schwab, Margo EOP/OMB

Subject: Re: briefings on OW actions

Ex. 6 Personal Privacy (PP)

Caryn,

I am out of the office until Tuesday so please work with Margo to set up the peer review briefing.

Thanks,

Vlad

Sent from my iPhone

On Jun 15, 2017, at 7:58 AM, Muellerleile, Caryn <Muellerleile.Caryn@epa.gov> wrote:

Hello Vlad,

I am coordinating another OW briefing on perchlorate peer review. OW has a tight timeline due to a deadline (explanation in blue text further below).

We have the following date & time suggestions for this briefing:

- 6/29/17 (Thurs) 11-12 or 3-4
- 6/30/17 (Fri) 9-10
- 7/3/17 (Mon) 10-11 or 11-12

Please let me know if you have questions or alternate suggestions. OW is working on materials to share with interagency partners for this briefing.

Thank you,

Caryn

202-564-2855

The perchlorate SDWA action has deadlines that are established under a consent decree. The first consent decree deadline is for completion of the expert peer review by October 18, 2017 of materials to inform EPA's SDWA action on perchlorate. While this is a unenforceable date, the EPA would need to file a letter with the court explaining why we did not meet the deadline. The consent decree also established enforceable deadlines of October 2018 for a proposal and December 2019 for final. Delay in completing the expert peer review will severely limit the timeframe for EPA to develop a proposal.

From: Dorjets, Vlad **Ex. 6 Personal Privacy (PP)**

Sent: Wednesday, June 15, 2016 11:03 AM

To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>

Subject: RE: briefings on OW actions

Thanks for setting this up. I need to coordinate with some other folks over here and will get back to you.

From: Muellerleile, Caryn [<mailto:Muellerleile.Caryn@epa.gov>]

Sent: Tuesday, June 14, 2016 5:01 PM

To: Dorjets, Vlad **Ex. 6 Personal Privacy (PP)**

Subject: RE: briefings on OW actions

Hello Vlad,

Regarding the Perchlorate peer review activities briefing with OW, a few date/time offerings:

Monday, June 20 @ 2:00 p.m.

Wed., June 22 @ 9:00 a.m.

Thurs, June 30 @ 2 p.m. or 3 p.m.

Caryn Muellerleile
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From: Dorjets, Vlad **Ex. 6 Personal Privacy (PP)**

Sent: Tuesday, June 07, 2016 3:09 PM

To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>

Subject: RE: briefings on OW actions

Thanks for checking. I actually don't remember what prompted my request for a briefing on stormwater but I'm sure there was a reason. I can definitely confirm the other two. Also, I sent a request to Nicole this morning for yet another briefing. I'll forward that email you right away.

From: Muellerleile, Caryn [<mailto:Muellerleile.Caryn@epa.gov>]

Sent: Tuesday, June 07, 2016 3:05 PM

To: Dorjets, Vlad **Ex. 6 Personal Privacy (PP)**

Subject: briefings on OW actions

Hello Vlad,

Just checking in, as I understand there have been various requests on informational briefings on OW topics and I don't want to lose track of them all.

- 1) The Forest Roads update is scheduled for next Tuesday, 6/14 at 3:15. I hope that one still works for you.
- 2) Stormwater (overall status update) was something you requested during Reg Agenda review. I will schedule that in the near future, unless your request has changed in any way.
- 3) Peer review in perchlorate (ground water/drinking water). This one just came in to me from Nicole, but I can't schedule yet as many OW staff are out an SES conference. For this one, I hope to discuss potential schedule options with you next week.

Is there anything else I'm missing? Also, we will soon be sending another list of requests of non-significance for various OW rules, but that is not quite ready yet. At that time there may be additional questions or potential briefings to schedule.

Thank you,
Caryn

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Message

From: Christ, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10DBD8E424704E43B5A50F74A4DAC626-LCHRIST]
Sent: 7/7/2017 1:14:53 PM
To: Mclain, Jennifer [Mclain.Jennifer@epa.gov]
Subject: RE: briefings on OW actions

perfect

From: Mclain, Jennifer
Sent: Friday, July 07, 2017 9:09 AM
To: Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: briefings on OW actions

Yes, I would respond that we will be providing the briefing materials and charge questions prior to the meeting as we did for the first round. We agree that it would be helpful for everyone to have these a few days ahead of time. It would probably be helpful to share the agenda or confirm that we will be covering the comments/model changes as well as the MCLG.

So, assuming we can get the materials out early next week, we could push back the meeting to the end of next week or the beginning of the week of July 17th.

How does that sound?

From: Christ, Lisa
Sent: Friday, July 07, 2017 8:56 AM
To: Mclain, Jennifer <Mclain.Jennifer@epa.gov>
Subject: FW: briefings on OW actions
Importance: High

We did not intend to provide the draft reports for review. The plan was to provide the draft charge for input prior to release for public comment. Depending on when the meeting is scheduled we could provide slides in advance??

From: Muellerleile, Caryn
Sent: Friday, July 07, 2017 8:52 AM
To: Christ, Lisa <Christ.Lisa@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>
Subject: FW: briefings on OW actions

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: Thursday, July 06, 2017 3:23 PM
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Caryn,

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Ex. 5 Deliberative Process (DP)

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Thank you,
Caryn
202-564-2855

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Thurs, June 30 @ 2 p.m. or 3 p.m.

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Sent: Tuesday, June 07, 2016 3:09 PM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>
Subject: RE: briefings on OW actions

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Sent: Tuesday, June 07, 2016 3:05 PM
To: Dorjets, Vlad [Ex. 6 Personal Privacy (PP)]
Subject: briefings on OW actions

Hello Vlad,

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Ex. 5 Deliberative Process (DP)

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Thank you,
Caryn

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Message

From: Colip, Matthew [colip.matthew@epa.gov]
Sent: 7/3/2017 7:13:32 PM
To: Davis, Patrick [davis.patrick@epa.gov]; Brooks, Becky [Brooks.Becky@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Traylor, Patrick [traylor.patrick@epa.gov]; Gunasekara, Mandy [Gunasekara.Mandy@epa.gov]; Bolen, Brittany [bolen.brittany@epa.gov]
CC: Benjamin, Kent [Benjamin.Kent@epa.gov]
Subject: RE: FFRRO Technical Fact Sheets Update
Attachments: Perchlorate_FactSheet 4-24-17.docx; NDMA fact sheet update 1-19-17.docx; FFRROFactSheet_Contaminants_TNT_1-23-16.docx; FFRROFactSheet_Contaminants_TCP_1-23-17.docx; FFRROFactSheet_Contaminants_PFOS PFOA_4-10-17.docx; FFRRO_ECFactSheet_Tungsten_4-24-17.docx; FFRRO_ECFactSheet_RDX_4-24-17.docx; FFRRO FactSheet PBDE-PBB 012317.docx; FFRRO Fact Sheet-Nanomaterials_4-28-17.docx; FFRRO Fact Sheet -DNT_2-7-17.docx; 1-4-Dioxane fact sheet update 5-26-17.docx

Patrick,

Word docs attached. Copying others from earlier email.

Thanks - Matt

Matthew Colip
Office of Communications, Partnerships and Analysis
Office of Land and Emergency Management (OLEM)
U.S. Environmental Protection Agency
Office: 202-566-2641
Mobile: Ex. 6 Personal Privacy (PP)
[Follow us on Twitter @EPALand](#)

From: Davis, Patrick
Sent: Monday, July 03, 2017 11:50 AM
To: Colip, Matthew <colip.matthew@epa.gov>
Subject: FW: FFRRO Technical Fact Sheets Update

Matt,

FYI, If you have them in word format it would help with editing.

Thanks,

Patrick Davis
Environmental Protection Agency
Deputy Assistant Administrator, Office of Land and Emergency Management
202-564-3103 office
Ex. 6 Personal Privacy (PP) cell

Information sent to this email address may be subject to FOIA.

From: Beck, Nancy
Sent: Thursday, June 29, 2017 2:03 PM
To: Brooks, Becky <Brooks.Becky@epa.gov>; Forsgren, Lee <Forsgren.Lee@epa.gov>; Traylor, Patrick <traylor.patrick@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Bolen, Brittany

<bolen.brittany@epa.gov>

Cc: Davis, Patrick <davis.patrick@epa.gov>

Subject: RE: FFRRO Technical Fact Sheets Update

Becky,

Is it possible to get word versions for easier editing?

Also, is there a date by which you need input?

Thanks,

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

From: Brooks, Becky

Sent: Thursday, June 29, 2017 10:29 AM

To: Beck, Nancy <Beck.Nancy@epa.gov>; Forsgren, Lee <Forsgren.Lee@epa.gov>; Traylor, Patrick <traylor.patrick@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>

Cc: Davis, Patrick <davis.patrick@epa.gov>

Subject: FW: FFRRO Technical Fact Sheets Update

Attached are the documents referenced in the email you received from Patrick Davis on June 26, 2017, around 4:20 p.m. We heard from one office that the attachments didn't come through, so I am resending them to everyone on his email. Thanks.

Becky Brooks

Special Assistant

Office of Land and Emergency Management

U.S. Environmental Protection Agency

ph. 202-566-2762

From: Cooke, Maryt

Sent: Thursday, June 15, 2017 11:46 AM

To: Breen, Barry <Breen.Barry@epa.gov>; Davis, Patrick <davis.patrick@epa.gov>; Simon, Nigel <Simon.Nigel@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>

Cc: Lowery, Brigid <Lowery.Brigid@epa.gov>; Colip, Matthew <colip.matthew@epa.gov>; Young, Dianna <Young.Dianna@epa.gov>; Gervais, Gregory <Gervais.Gregory@epa.gov>

Subject: FFRRO Technical Fact Sheets Update

Barry/Patrick/Nigel –

FFRRO has updated our Technical Fact Sheets and I wanted to get your approval to move them through the OPA process in preparation of posting them online.

As background, FFRRO has been the lead on these Emerging Contaminant/Technical Fact Sheets since 2005. These fact sheets, available online on the FFRRO website and clu-in.org, provide a summary of the contaminant including physical and chemical properties; environmental and health impacts; existing federal and state guidelines; detection and treatment methods; and additional sources of information. They are generally intended for use by site managers and other field personnel who may address these contaminants at cleanup sites.

FFRRO has developed eleven Technical Fact Sheets based on the needs of EPA staff and in conjunction with the DoD Emerging Contaminants Watch List. They are 1,2,3-trichloropropane (TCP), 1,4-Dioxane, Nanomaterials, N-Nitrosodimethylamine (NDMA), Perchlorate, polybrominated diphenyl ethers (PBDE) and polybrominated biphenyls (PBB), Tungsten, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), dinitrotoluene (DNT), 2,4,6-trinitrotoluene (TNT), and hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX). While many of these compounds are more commonly associated with DoD they are not necessarily exclusive to the Services. These fact sheet are also accessed by and available to the public and we have received inquiries on many of them from all over the world.

The last update of the fact sheets occurred about 2 years ago. Since then much of the science and information surrounding these compounds has evolved. One fact sheet of note is the PFOA/PFOS fact sheet. Before the EPA HA was released FFRRO took the PFOA/PFOS factsheet offline so that no confusion would be created by conflicting information in an outdated fact sheet. We have updated the document to be consistent with the HA and most recent information. Several EPA offices have reviewed and offered input on these including OSRTI, ORD, PARMS. The PFOA/S fact sheet has also been reviewed by OW, OEM and ORCR.

We sent these to CPA in anticipation of getting your approval to move forward. Once approve they will continue through the OPA process.

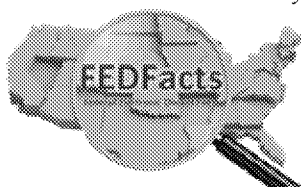
Please let me know if you have any questions or require any additional information. I look forward to your feedback.

Thank you

Mary T. Cooke
USEPA Headquarters
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 5106R (FFRRO)
Washington, DC 20460

Phone: 202-564-0788

Learn about Federal Facility Cleanups in your area:



Message

From: Forsgren, Lee [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A055D7329D5B470FBAA9920CE1B68A7D-FORSGREN, D]
Sent: 5/13/2020 8:06:16 PM
To: Spraul, Greg [Spraul.Greg@epa.gov]
CC: Charlotte Bertrand [Bertrand.Charlotte@epa.gov]
Subject: FW: SEPW Briefing Binder
Attachments: 2020.05.13 - Administrator Wheeler Full Budget Binder (2).zip

Greg,

For your master file.

Lee

From: Frye, Tony (Robert) <frye.robert@epa.gov>
Sent: Wednesday, May 13, 2020 3:50 PM
To: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Molina, Michael <molina.michael@epa.gov>; Hanson, Paige (Catherine) <hanson.catherine@epa.gov>; Benevento, Douglas <benevento.douglas@epa.gov>; Leopold, Matt (OGC) <Leopold.Matt@epa.gov>; Schiermeyer, Corry <schiermeyer.corry@epa.gov>; Bolen, Derrick <bolen.derrick@epa.gov>; Dankert, Charles M. (Charlie) <Dankert.Charles@epa.gov>; Bloom, David <Bloom.David@epa.gov>; Willey, Katharine <willey.katharine@epa.gov>; Idsal, Anne <idsal.anne@epa.gov>; Harlow, David <harlow.david@epa.gov>; Dominguez, Alexander <dominguez.alexander@epa.gov>; Moor, Karl <Moor.Karl@epa.gov>; Cory, Preston <Cory.Preston@epa.gov>; Raymond, Kelley <Raymond.Kelley@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Fischer, David <Fischer.David@epa.gov>; Bolen, Derrick <bolen.derrick@epa.gov>; Bodine, Susan <bodine.susan@epa.gov>; Tran, Victoria <tran.victoria@epa.gov>; Irving, John <Irving.John@epa.gov>; Coxen, Carrie <coxen.carrie@epa.gov>; Dunlap, David <dunlap.david@epa.gov>; Fitzmorris, Amanda <fitzmorris.amanda@epa.gov>; Jones, Lindsey <jones.lindsey@epa.gov>; Vizian, Donna <Vizian.Donna@epa.gov>; Zeckman, David <zeckman.david@epa.gov>; Ross, David P <ross.davidp@epa.gov>; Wildeman, Anna <wildeman.anna@epa.gov>; Forsgren, Lee <Forsgren.Lee@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; McIntosh, Chad <mcintosh.chad@epa.gov>; Zimmer, Nathaniel <zimmer.nathaniel@epa.gov>; Yarbrough, John (Daniel) <Yarbrough.Daniel@epa.gov>; Fotouhi, David <Fotouhi.David@epa.gov>; Cody, Meredith <cody.meredith@epa.gov>; Wright, Peter <wright.peter@epa.gov>; Hoverman, Taylor <hoverman.taylor@epa.gov>; Cook, Steven <cook.steven@epa.gov>
Cc: Brazauskas, Joseph <brazauskas.joseph@epa.gov>; Voyles, Travis <Voyles.Travis@epa.gov>; Edwards, John (Holt) <edwards.john@epa.gov>
Subject: RE: SEPW Briefing Binder

2 of 2 – PLEASE LIMIT DISTRIBUTION AS APPROPRIATE

Full binder attached.

Tony Frye
Director of Senate Affairs
Office of Congressional Affairs
Environmental Protection Agency
Cell: Ex. 6 Personal Privacy (PP)

From: Frye, Tony (Robert)
Sent: Wednesday, May 13, 2020 3:47 PM

To: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Michael Molina (molina.michael@epa.gov) <molina.michael@epa.gov>; Hanson, Paige (Catherine) <hanson.catherine@epa.gov>; Benevento, Douglas <benevento.douglas@epa.gov>; Leopold, Matt (OGC) <Leopold.Matt@epa.gov>; Schiermeyer, Corry <schiermeyer.corry@epa.gov>; Bolen, Derrick <bolen.derrick@epa.gov>; Dankert, Charles M. (Charlie) <Dankert.Charles@epa.gov>; Bloom, David <Bloom.David@epa.gov>; Willey, Katharine <willey.katharine@epa.gov>; Idsal, Anne <idsal.anne@epa.gov>; Harlow, David <harlow.david@epa.gov>; Dominguez, Alexander <dominguez.alexander@epa.gov>; Moor, Karl <Moor.Karl@epa.gov>; Cory, Preston <Cory.Preston@epa.gov>; Raymond, Kelley <Raymond.Kelley@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Fischer, David <Fischer.David@epa.gov>; Bolen, Derrick <bolen.derrick@epa.gov>; Bodine, Susan <bodine.susan@epa.gov>; Tran, Victoria <tran.victoria@epa.gov>; Irving, John <Irving.John@epa.gov>; Coxen, Carrie <coxen.carrie@epa.gov>; Dunlap, David <dunlap.david@epa.gov>; Fitzmorris, Amanda <fitzmorris.amanda@epa.gov>; Jones, Lindsey <jones.lindsey@epa.gov>; Vizian, Donna <Vizian.Donna@epa.gov>; Zeckman, David <zeckman.david@epa.gov>; Ross, David P <ross.davidp@epa.gov>; Wildeman, Anna <wildeman.anna@epa.gov>; Forsgren, Lee <Forsgren.Lee@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; McIntosh, Chad <mcintosh.chad@epa.gov>; Zimmer, Nathaniel <zimmer.nathaniel@epa.gov>; Yarbrough, John (Daniel) <Yarbrough.Daniel@epa.gov>; Fotouhi, David <fotouhi.david@epa.gov>; Cody, Meredith <cody.meredith@epa.gov>; Wright, Peter <wright.peter@epa.gov>; Hoverman, Taylor <hoverman.taylor@epa.gov>; Cook, Steven <cook.steven@epa.gov>
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Best,
Tony

Tony Frye
Director of Senate Affairs
Office of Congressional Affairs
Environmental Protection Agency
Cell: Ex. 6 Personal Privacy (PP)

Message

From: Willey, Katharine [willey.katharine@epa.gov]
Sent: 5/13/2020 8:12:30 PM
To: Fotouhi, David [Fotouhi.David@epa.gov]; Lis-Coghlan, Kamila [lis-coghlan.kamila@epa.gov]; Gustafson, Adam [Gustafson.Adam@epa.gov]
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Director of Senate Affairs

Office of Congressional Affairs

Environmental Protection Agency

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Tony

Tony Frye
Director of Senate Affairs
Office of Congressional Affairs
Environmental Protection Agency
Cell: Ex. 6 Personal Privacy (PP)

Message

From: Willey, Katharine [willey.katharine@epa.gov]
Sent: 5/14/2020 2:38:57 PM
To: Leopold, Matt (OGC) [Leopold.Matt@epa.gov]; Fotouhi, David [Fotouhi.David@epa.gov]
Subject: FW: SEPW Briefing Binder
Attachments: 2020.05.13 - Administrator Wheeler Full Budget Binder (2).zip

From: Willey, Katharine
Sent: Wednesday, May 13, 2020 4:13 PM
To: Fotouhi, David <fotouhi.david@epa.gov>; Lis-Coghlan, Kamila <lis-coghlan.kamila@epa.gov>; Gustafson, Adam <Gustafson.Adam@epa.gov>
Subject: FW: SEPW Briefing Binder

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Sent: Wednesday, May 13, 2020 3:50 PM
To: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Molina, Michael <molina.michael@epa.gov>; Hanson, Paige (Catherine) <hanson.catherine@epa.gov>; Benevento, Douglas <benevento.douglas@epa.gov>; Leopold, Matt (OGC) <Leopold.Matt@epa.gov>; Schiermeyer, Corry <schiermeyer.corry@epa.gov>; Bolen, Derrick <bolen.derrick@epa.gov>; Dankert, Charles M. (Charlie) <Dankert.Charles@epa.gov>; Bloom, David <Bloom.David@epa.gov>; Willey, Katharine <willey.katharine@epa.gov>; Idsal, Anne <idsal.anne@epa.gov>; Harlow, David <harlow.david@epa.gov>; Dominguez, Alexander <dominguez.alexander@epa.gov>; Moor, Karl <Moor.Karl@epa.gov>; Cory, Preston <Cory.Preston@epa.gov>; Raymond, Kelley <Raymond.Kelley@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Fischer, David <Fischer.David@epa.gov>; Bolen, Derrick <bolen.derrick@epa.gov>; Bodine, Susan <bodine.susan@epa.gov>; Tran, Victoria <tran.victoria@epa.gov>; Irving, John <Irving.John@epa.gov>; Coxen, Carrie <coxen.carrie@epa.gov>; Dunlap, David <dunlap.david@epa.gov>; Fitzmorris, Amanda <fitzmorris.amanda@epa.gov>; Jones, Lindsey <jones.lindsey@epa.gov>; Vizian, Donna <Vizian.Donna@epa.gov>; Zeckman, David <zeckman.david@epa.gov>; Ross, David P <ross.davidp@epa.gov>; Wildeman, Anna <wildeman.anna@epa.gov>; Forsgren, Lee <Forsgren.Lee@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; McIntosh, Chad <mcintosh.chad@epa.gov>; Zimmer, Nathaniel <zimmer.nathaniel@epa.gov>; Yarbrough, John (Daniel) <Yarbrough.Daniel@epa.gov>; Fotouhi, David <Fotouhi.David@epa.gov>; Cody, Meredith <cody.meredith@epa.gov>; Wright, Peter <wright.peter@epa.gov>; Hoverman, Taylor <hoverman.taylor@epa.gov>; Cook, Steven <cook.steven@epa.gov>
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Tony Frye
Director of Senate Affairs
Office of Congressional Affairs
Environmental Protection Agency
Cell: Ex. 6 Personal Privacy (PP)

Message

From: Miles-McLean, Stuart [Miles-McLean.Stuart@epa.gov]
Sent: 2/13/2019 6:06:08 PM
To: OP-ORPM-PRAD [OPORPMPRAD@epa.gov]
Subject: FW FYI: OP Spring 2019 Reg Agenda Data Call
Attachments: Fall-2018-Published_EPA_AgendaPlan.xlsx; ADPTracker-Report-RegAgenda_01-30-2019.xlsx; Spring 2019 Regulatory Agenda Review Instructions.docx

FYI

=====

From: Wiggins, Lanelle
Sent: Tuesday, February 12, 2019 3:35 PM
To: RSC Core <RSC_Core@epa.gov>; Moore, Sonya <Moore.Sonya@epa.gov>; Zull, Aaron <zull.aaron@epa.gov>; Morales, Monica <Morales.Monica@epa.gov>; Tyler, Kendra <Tyler.Kendra@epa.gov>; Young, Margo <Young.Margo@epa.gov>
Cc: RMD Desk Officers <RMD_DO@epa.gov>
Subject: FW: OP Spring 2019 Reg Agenda Data Call

Hi All,

I know it is only one extra day, but I'm sure you can use it...

Please make changes to your Reg. Agenda entries or enter additional Reg. Agenda entries, with OP's and OGC's reviews, by **Tuesday, February 19, 2019**.

Thanks,
Lanelle

Lanelle Bembenek Wiggins

Acting Division Director, Regulatory Management Division
US EPA - Office of Policy (1803A) - 1200 Penn Ave NW - Washington DC - 20460
202.566.2372

From: Muellerleile, Caryn
Sent: Thursday, January 31, 2019 5:07 PM
To: RSC Core <RSC_Core@epa.gov>; Moore, Sonya <Moore.Sonya@epa.gov>; Zull, Aaron <zull.aaron@epa.gov>; Morales, Monica <Morales.Monica@epa.gov>; Tyler, Kendra <Tyler.Kendra@epa.gov>; Young, Margo <Young.Margo@epa.gov>
Cc: Wiggins, Lanelle <Wiggins.Lanelle@epa.gov>; Adams, Darryl <Adams.Darryl@epa.gov>; RMD Desk Officers <RMD_DO@epa.gov>
Subject: OP Spring 2019 Reg Agenda Data Call

Greetings,

For those unable to attend this morning's RSC meeting due to conflict or phone issues, please see the information below.

* Quick Update on Lotus Notes and access to ADP Tracker & FR Dailies *

- The 9/27/2018 RSC meeting contained mention of acquiring a Lotus Notes license for CY-2019 in order to continue using ADP Tracker and/or FR Dailies. ([summary on the 10/11/18 page](#)).

- Individuals who find themselves without Notes access now need to contact their Information Management Officers (IMO); it is unclear whether being added to Notes is going to be easy or difficult or if it will vary by office.
- IMO list is available [here](#).
- All of the information below and the attachments to this message are mechanisms to try to help you work on this Reg. Agenda cycle outside of Lotus Notes, if necessary.

Spring 2019 Reg Agenda

- OP does not yet have OMB's call letter, but we are told it is coming soon. If possible, we will extend the due date for entries after receipt of the call letter. For now, expect that OP will request your response with modifications to entries by COB **Friday, February 15, 2019**.
- The acting Administrator has expressed interest in reviewing EPA's spring agenda, so please give additional scrutiny to your offices' entries, particularly those of higher tier levels.
- The attached spreadsheet of fall 2018 entries is a reference for you to see how most actions appeared in the current publication.
- The attached ADP Report spreadsheet, dated 1-30-2019, contains the compiled list of current and new Reg. Agenda Entries, and some key data for each. Note: time table information in this spreadsheet is likely to be more out-of-date than what appeared in the fall 2018 agenda or in the action's current timetable. This is because ADP Reporting pulled data from the Reg. Agenda Entry submitted by your AAship last August (2018).
- The attached Spring 2019 Instructions document is meant to help you update most key pieces of data for existing Agenda entries without using Lotus Notes. Using the ADP Report spreadsheet, make updates to actions in appropriate cells and highlight any cell that has been modified.
- Changes to Reg. Agenda entries will need to be made, with OP's and OGC's reviews, by ~~Friday, February 15, 2019~~. Whether someone in your office does this in ADP Tracker and submits using the standard Reg Agenda workflow, or if you elect to send your spreadsheet edits to your [RMD Desk Officer](#), is up to you based on Lotus Notes access. Note that OGC attorneys will not be able to review in Lotus Notes.

This information is also available at the RSC SharePoint site at [Spring 2019 Agenda](#).

Caryn Muellerleile
Regulatory Management Division
Office of Policy
US Environmental Protection Agency
1200 Pennsylvania Ave NW (1803A)
Washington, DC 20460
(202) 564-2855
muellerleile.caryn@epa.gov

Message

From: Miles-McLean, Stuart [Miles-McLean.Stuart@epa.gov]
Sent: 2/1/2019 11:33:20 PM
To: OP-ORPM-PRAD [OPORPMPRAD@epa.gov]
Subject: FW FYI - OP Spring 2019 Reg Agenda Data Call
Attachments: Fall-2018-Published_EPA_AgendaPlan.xlsx; ADPTracker-Report-RegAgenda_01-30-2019.xlsx; Spring 2019 Regulatory Agenda Review Instructions.docx

Hello PRADists,

I know Bridgid already alerted you to the initiation of the Spring 2019 Reg Agenda process, but I thought you might be interested in seeing what went to the programs (below and attached).

I also want to flag for you two bullets from RMD's email:

- The acting Administrator has expressed interest in reviewing EPA's spring agenda, so please give additional scrutiny to your offices' entries, particularly those of higher tier levels.
- Changes to Reg. Agenda entries will need to be made, with OP's and OGC's reviews, by **Friday, February 15, 2019**.

Additional scrutiny and a short time frame.

Thanks for your attention, Stuart

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- Individuals who find themselves without Notes access now need to contact their Information Management Officers (IMO); it is unclear whether being added to Notes is going to be easy or difficult or if it will vary by office.
- IMO list is available [here](#).
- All of the information below and the attachments to this message are mechanisms to try to help you work on this Reg. Agenda cycle outside of Lotus Notes, if necessary.

Spring 2019 Reg Agenda

- OP does not yet have OMB's call letter, but we are told it is coming soon. If possible, we will extend the due date for entries after receipt of the call letter. For now, expect that OP will request your response with modifications to entries by COB Friday, February 15, 2019.
- The acting Administrator has expressed interest in reviewing EPA's spring agenda, so please give additional scrutiny to your offices' entries, particularly those of higher tier levels.
- The attached spreadsheet of fall 2018 entries is a reference for you to see how most actions appeared in the current publication.
- The attached ADP Report spreadsheet, dated 1-30-2019, contains the compiled list of current and new Reg. Agenda Entries, and some key data for each. Note: time table information in this spreadsheet is likely to be more out-of-date than what appeared in the fall 2018 agenda or in the action's current timetable. This is because ADP Reporting pulled data from the Reg. Agenda Entry submitted by your AAship last August (2018).
- The attached Spring 2019 Instructions document is meant to help you update most key pieces of data for existing Agenda entries without using Lotus Notes. Using the ADP Report spreadsheet, make updates to actions in appropriate cells and highlight any cell that has been modified.
- Changes to Reg. Agenda entries will need to be made, with OP's and OGC's reviews, by Friday, February 15, 2019. Whether someone in your office does this in ADP Tracker and submits using the standard Reg Agenda workflow, or if you elect to send your spreadsheet edits to your RMD Desk Officer, is up to you based on Lotus Notes access. Note that OGC attorneys will not be able to review in Lotus Notes.

This information is also available at the RSC SharePoint site at [Spring 2019 Agenda](#).

Caryn Muellerleile
Regulatory Management Division
Office of Policy
US Environmental Protection Agency
1200 Pennsylvania Ave NW (1803A)
Washington, DC 20460
(202) 564-2855
muellerleile.caryn@epa.gov

Message

From: Willey, Katharine [willey.katharine@epa.gov]
Sent: 5/18/2020 8:36:29 PM
To: Leopold, Matt (OGC) [Leopold.Matt@epa.gov]
Subject: FW: SEPW Briefing Binder
Attachments: 2020.05.13 - Administrator Wheeler Full Budget Binder (2).zip

Fact Sheets are in the OCFO/OCIR folder for this afternoon.

From: Frye, Tony (Robert) <frye.robert@epa.gov>
Sent: Wednesday, May 13, 2020 3:50 PM
To: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Molina, Michael <molina.michael@epa.gov>; Hanson, Paige (Catherine) <hanson.catherine@epa.gov>; Benevento, Douglas <benevento.douglas@epa.gov>; Leopold, Matt (OGC) <Leopold.Matt@epa.gov>; Schiermeyer, Corry <schiermeyer.corry@epa.gov>; Bolen, Derrick <bolen.derrick@epa.gov>; Dankert, Charles M. (Charlie) <Dankert.Charles@epa.gov>; Bloom, David <Bloom.David@epa.gov>; Willey, Katharine <willey.katharine@epa.gov>; Idsal, Anne <idsal.anne@epa.gov>; Harlow, David <harlow.david@epa.gov>; Dominguez, Alexander <dominguez.alexander@epa.gov>; Moor, Karl <Moor.Karl@epa.gov>; Cory, Preston <Cory.Preston@epa.gov>; Raymond, Kelley <Raymond.Kelley@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Fischer, David <Fischer.David@epa.gov>; Bolen, Derrick <bolen.derrick@epa.gov>; Bodine, Susan <bodine.susan@epa.gov>; Tran, Victoria <tran.victoria@epa.gov>; Irving, John <Irving.John@epa.gov>; Coxen, Carrie <coxen.carrie@epa.gov>; Dunlap, David <dunlap.david@epa.gov>; Fitzmorris, Amanda <fitzmorris.amanda@epa.gov>; Jones, Lindsey <jones.lindsey@epa.gov>; Vizian, Donna <Vizian.Donna@epa.gov>; Zeckman, David <zeckman.david@epa.gov>; Ross, David P <ross.davidp@epa.gov>; Wildeman, Anna <wildeman.anna@epa.gov>; Forsgren, Lee <Forsgren.Lee@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; McIntosh, Chad <mcintosh.chad@epa.gov>; Zimmer, Nathaniel <zimmer.nathaniel@epa.gov>; Yarbrough, John (Daniel) <Yarbrough.Daniel@epa.gov>; Fotouhi, David <Fotouhi.David@epa.gov>; Cody, Meredith <cody.meredith@epa.gov>; Wright, Peter <wright.peter@epa.gov>; Hoverman, Taylor <hoverman.taylor@epa.gov>; Cook, Steven <cook.steven@epa.gov>
Cc: Brazauskas, Joseph <brazauskas.joseph@epa.gov>; Voyles, Travis <Voyles.Travis@epa.gov>; Edwards, John (Holt) <edwards.john@epa.gov>
Subject: RE: SEPW Briefing Binder

2 of 2 – PLEASE LIMIT DISTRIBUTION AS APPROPRIATE

Full binder attached.

Tony Frye
Director of Senate Affairs
Office of Congressional Affairs
Environmental Protection Agency
Cell: Ex. 6 Personal Privacy (PP)

From: Frye, Tony (Robert)
Sent: Wednesday, May 13, 2020 3:47 PM
To: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Michael Molina (molina.michael@epa.gov) <molina.michael@epa.gov>; Hanson, Paige (Catherine) <hanson.catherine@epa.gov>; Benevento, Douglas <benevento.douglas@epa.gov>; Leopold, Matt (OGC) <Leopold.Matt@epa.gov>; Schiermeyer, Corry <schiermeyer.corry@epa.gov>; Bolen, Derrick <bolen.derrick@epa.gov>; Dankert, Charles M. (Charlie) <Dankert.Charles@epa.gov>; Bloom, David <Bloom.David@epa.gov>; Willey, Katharine <willey.katharine@epa.gov>; Idsal, Anne <idsal.anne@epa.gov>; Harlow, David <harlow.david@epa.gov>; Dominguez, Alexander

<dominguez.alexander@epa.gov>; Moor, Karl <Moor.Karl@epa.gov>; Cory, Preston <Cory.Preston@epa.gov>; Raymond, Kelley <Raymond.Kelley@epa.gov>; Tardif, Abigale (Abbie) <Tardif.Abigale@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Fischer, David <Fischer.David@epa.gov>; Bolen, Derrick <bolen.derrick@epa.gov>; Bodine, Susan <bodine.susan@epa.gov>; Tran, Victoria <tran.victoria@epa.gov>; Irving, John <Irving.John@epa.gov>; Coxen, Carrie <coxen.carrie@epa.gov>; Dunlap, David <dunlap.david@epa.gov>; Fitzmorris, Amanda <fitzmorris.amanda@epa.gov>; Jones, Lindsey <jones.lindsey@epa.gov>; Vizian, Donna <Vizian.Donna@epa.gov>; Zeckman, David <zeckman.david@epa.gov>; Ross, David P <ross.davidp@epa.gov>; Wildeman, Anna <wildeman.anna@epa.gov>; Forsgren, Lee <Forsgren.Lee@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; McIntosh, Chad <mcintosh.chad@epa.gov>; Zimmer, Nathaniel <zimmer.nathaniel@epa.gov>; Yarbrough, John (Daniel) <Yarbrough.Daniel@epa.gov>; Fotouhi, David <fotouhi.david@epa.gov>; Cody, Meredith <cody.meredith@epa.gov>; Wright, Peter <wright.peter@epa.gov>; Hoverman, Taylor <hoverman.taylor@epa.gov>; Cook, Steven <cook.steven@epa.gov>
Cc: Brazauskas, Joseph <brazauskas.joseph@epa.gov>; Voyles, Travis <Voyles.Travis@epa.gov>; Edwards, John (Holt) <edwards.john@epa.gov>

Subject: SEPW Briefing Binder

1 of 2 – PLEASE LIMIT DISTRIBUTION AS APPROPRIATE

Hello All – I apologize for my delay in sending these documents around, there are still some moving parts, but we wanted to get the majority of what is finalized to you before the last hold outs.

Attached, please find the truncated SEPW hearing binder that is currently with the Administrator for his review prior to briefings this week in advance of his hearing Wednesday. All of the sheets in this file should be highlighted in the attached TOC.

Following this email, I will send another with the full binder that reflects all of the documents on the TOC, the file is simply too large to get into one email.

There have been a lot of moving parts in this process, please let me know if you have any questions, think I missed a sheet your office provided to OCIR, or have any comments.

Have a great day!

Best,
Tony

Tony Frye
Director of Senate Affairs
Office of Congressional Affairs
Environmental Protection Agency
Cell: Ex. 6 Personal Privacy (PP)

Message

From: Nickerson, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=148F2C1C05B54F358E29C59B841664AA-WNICKER]
Sent: 6/16/2020 8:45:54 PM
To: Tyree, Robin [Tyree.Robin@epa.gov]; Veney, Carla [Veney.Carla@epa.gov]; Yarbrough, John (Daniel) [Yarbrough.Daniel@epa.gov]; Dziadosz, Patricia [Dziadosz.Patricia@epa.gov]
CC: Corrales, Mark [Corrales.Mark@epa.gov]; Manibusan, Mary [Manibusan.Mary@epa.gov]
Subject: for BB reading file and discussion with the Administrator tomorrow
Attachments: Taconite Iron Ore Processing RTR final 2020-06-02 OP Review Summary.pdf; SAN 6934 Misc Coating Manufacturing RTR final 2020-06-02 OP Review Summary.pdf; SAN# 6494 MON Inadvertent Errors Memo 061220 (003).pdf; MON Inadvertent Errors OGC Concurrence.docx; guidance portal stats.docx; Process for Administrator signature of Federal Register documents from OCSPP that are not rules.docx; FRL 10011-02-OW.WIFIA Criteria FRNclean.unsigned.docx; SAN 7697 Pesticides ESA Report to Congress 2020-06-16 OP Review Summary.pdf

This is my attempt to be comprehensive about what is on the horizon and what might be ripe for discussion with the Administrator tomorrow.

Actions to be signed on Wednesday

- Dust Lead (not in OP yet)
- Perchlorate (not in OP yet)
- WIFIA FRN. (this outlines the criteria for WIFIA loans; the notice has to be signed by the Administrator, Russ Vought, and Steve Mnuchin with the intent that the Administrator sign first; latest version of the notice attached, but this is not yet ready for signature because the FR edits haven't been incorporated yet)
- Taconite RTR (in OP, ready, 1 pager attached)
- Miscellaneous Coatings RTR (in OP, ready, 1 pager attached)
- MON inadvertent errors correction memo (attached for reference with the intent of having AO staff "sign" the pdf on the Administrator's behalf; OGC approval on the memo also attached)

Actions ready to go to OMB

- Pesticide Report to Congress (in OP for OMB review, 1 pager attached; OCSPP would like this to go to OMB by Friday)

Other possible questions

- PFAS SNUR to be signed on Monday (not in OP yet). How to orchestrate that with the Administrator's travel?

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

- Process for Administrator signature of Federal Register documents from OCSPP that are not rules. Paper on this attached.

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 3/5/2019 10:21:03 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Vlad Dorjets [Ex. 6 Personal Privacy (PP)]; Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Johnson, Ann [Johnson.Ann@epa.gov]
BCC: DCRoomEast2418/DC-ICC-OW-OGWDW [DCRoomEast2418DC@epa.gov]
Subject: Perchlorate Proposed NPDWR
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)]
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Busy

Appointment

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 3/11/2019 5:12:16 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Burneson, Eric [Burneson.Eric@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Thomas, Amanda L. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Glass, Jacob S. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Theroux, Rich P. EOP/OMB [Ex. 6 Personal Privacy (PP)]

Subject: Perchlorate
Location: Dial-in [Ex. 6 Personal Privacy (PP)]

Start: 3/11/2019 8:00:00 PM
End: 3/11/2019 8:30:00 PM
Show Time As: Tentative

Recurrence: (none)

Appointment

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 3/11/2019 5:12:10 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Thomas, Amanda L. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Glass, Jacob S. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Theroux, Rich P. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: Perchlorate
Location: Dial-in [Ex. 6 Personal Privacy (PP)]
Start: 3/11/2019 8:00:00 PM
End: 3/11/2019 8:30:00 PM
Show Time As: Tentative

Recurrence: (none)

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 3/5/2019 10:21:07 PM
To: Vlad Dorjets [Ex. 6 Personal Privacy (PP)] Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]
BCC: DCRoomEast2418/DC-ICC-OW-OGWDW [DCRoomEast2418DC@epa.gov]
Subject: Perchlorate Proposed NPDWR
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)]
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Tentative

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 3/5/2019 10:21:03 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Vlad Dorjets [Ex. 6 Personal Privacy (PP)]
[Ex. 6 Personal Privacy (PP)] Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov];
Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Vlad Dorjets
[Ex. 6 Personal Privacy (PP)] Hernandez-Quinones, Samuel
[hernandez.samuel@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen
[Flaherty.Colleen@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)] Johnson, Ann
[Johnson.Ann@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]
BCC: DCRoomEast2418/DC-ICC-OW-OGWDW [DCRoomEast2418DC@epa.gov]
Subject: Perchlorate Proposed NPDWR
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)]
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Busy

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 3/5/2019 10:21:03 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Vlad Dorjets [Ex. 6 Personal Privacy (PP)]
[Ex. 6 Personal Privacy (PP)] Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov];
Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen
[Flaherty.Colleen@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]
BCC: DCRoomEast2418/DC-ICC-OW-OGWDW [DCRoomEast2418DC@epa.gov]
Subject: Perchlorate Proposed NPDWR
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)]
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Busy

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 3/5/2019 10:21:03 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Vlad Dorjets **Ex. 6 Personal Privacy (PP)**
Ex. 6 Personal Privacy (PP) Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]
BCC: DCRoomEast2418/DC-ICC-OW-OGWDW [DCRoomEast2418DC@epa.gov]
Subject: Perchlorate Proposed NPDWR
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in **Ex. 6 Personal Privacy (PP)**
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Busy

Appointment

From: Schwab, Margo EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: 3/5/2019 10:52:01 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]

Subject: Accepted: FW: Perchlorate Proposed NPDWR
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in **Ex. 6 Personal Privacy (PP)**

Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Busy

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 3/7/2019 8:02:44 PM
To: Vlad Dorjets [Ex. 6 Personal Privacy (PP)] Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)] Johnson, Ann [Johnson.Ann@epa.gov]
BCC: DCRoomEast2418/DC-ICC-OW-OGWDW [DCRoomEast2418DC@epa.gov]
Subject: Perchlorate Proposed NPDWR
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)]
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Tentative

Appointment

From: Jones, Lisa M. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 4/23/2019 8:38:57 PM
To: Mancini, Dominic J. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Theroux, Rich P. EOP/OMB
[Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Thomas, Amanda L.
EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)];
Kluever, April N. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Glass, Jacob S. EOP/OMB [Ex. 6 Personal Privacy (PP)];
Falk Curtin, Edna T. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Nickerson, William [Nickerson.William@epa.gov];
Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]
Subject: E.O. 12866 MTG re: National Primary Drinking Water Regulations: Regulation of Perchlorate (RIN 2040-AF28)
Location: Room 9258, New Executive Office Building (NEOB)/OMB - 725 17th Street, NW, Washington, DC 20503
Start: 4/30/2019 8:00:00 PM
End: 4/30/2019 8:30:00 PM
Show Time As: Tentative

Recurrence: (none)

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 4/25/2019 1:47:05 PM
To: Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]
CC: Johnson, Ann [Johnson.Ann@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Vladik_Dorjets [Ex. 6 Personal Privacy (PP)]
BCC: DCRoomEast2339/DC-ICC-OW-OGWDW [DCRoomEast2339@epa.gov]
Subject: Inter Agency Briefing on Proposed Perchlorate NPDWR
Location: DCRoomEast2339/DC-ICC-OW-OGWDW call in [Ex. 6 Personal Privacy (PP)]
Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Tentative

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 4/16/2019 4:42:03 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]
CC: Johnson, Ann [Johnson.Ann@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Vladik_Dorjets [Ex. 6 Personal Privacy (PP)]
BCC: DCRoomEast2339/DC-ICC-OW-OGWDW [DCRoomEast2339@epa.gov]
Subject: Inter Agency Briefing on Proposed Perchlorate NPDWR
Location: DCRoomEast2339/DC-ICC-OW-OGWDW call in [Ex. 6 Personal Privacy (PP)]
Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Busy

Appointment

From: Jones, Lisa M. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 4/23/2019 8:39:02 PM
To: Jones, Lisa M. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Mancini, Dominic J. EOP/OMB
[Ex. 6 Personal Privacy (PP)]; Theroux, Rich P. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad
[Ex. 6 Personal Privacy (PP)]; Thomas, Amanda L. EOP/OMB [Ex. 6 Personal Privacy (PP)];
Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Kluever, April N. EOP/OMB
[Ex. 6 Personal Privacy (PP)]; Glass, Jacob S. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Falk Curtin, Edna T.
EOP/OMB [Ex. 6 Personal Privacy (PP)]; Nickerson, William [Nickerson.William@epa.gov]; Burneson, Eric
[Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]

Subject: E.O. 12866 MTG re: National Primary Drinking Water Regulations: Regulation of Perchlorate (RIN 2040-AF28)
Location: Room 9258, New Executive Office Building (NEOB)/OMB - 725 17th Street, NW, Washington, DC 20503

Start: 4/30/2019 8:00:00 PM
End: 4/30/2019 8:30:00 PM
Show Time As: Tentative

Recurrence: (none)

Appointment

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: 4/18/2019 2:18:34 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]

Subject: Accepted: FW: Hold for Inter Agency Briefing on Proposed Perchlorate NPDWR
Location: DCRoomEast2339/DC-ICC-OW-OGWDW

Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Busy

Recurrence: (none)

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 4/16/2019 4:42:03 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]
CC: Johnson, Ann [Johnson.Ann@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Vladik_Dorjets [Ex. 6 Personal Privacy (PP)]
BCC: DCRoomEast2339/DC-ICC-OW-OGWDW [DCRoomEast2339@epa.gov]
Subject: Hold for Inter Agency Briefing on Proposed Perchlorate NPDWR
Location: DCRoomEast2339/DC-ICC-OW-OGWDW
Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Busy

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 4/16/2019 4:42:03 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]
CC: Johnson, Ann [Johnson.Ann@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Vladik_Dorjets([REDACTED])
BCC: DCRoomEast2339/DC-ICC-OW-OGWDW [DCRoomEast2339@epa.gov]
Subject: Hold for Inter Agency Briefing on Proposed Perchlorate NPDWR
Location: DCRoomEast2339/DC-ICC-OW-OGWDW
Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Busy

Appointment

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: 5/20/2019 6:19:02 PM
To: eric.t.gormsen@usdoj.gov; Oakes, Matthew (ENRD) [Matthew.Oakes@usdoj.gov]; Eric.Hostetler@usdoj.gov; Nickerson, William [Nickerson.William@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]

Subject: EPA Perchlorate MCL NPRM
Location: Dial-in: **Ex. 6 Personal Privacy (PP)**

Start: 5/20/2019 8:00:00 PM
End: 5/20/2019 8:30:00 PM
Show Time As: Tentative

Recurrence: (none)

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 3/29/2019 1:55:29 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
CC: Nickerson, William [Nickerson.William@epa.gov]

Subject: Follow up on perchlorate
Location: call in: **Ex. 6 Personal Privacy (PP)**

Start: 3/29/2019 5:00:00 PM
End: 3/29/2019 5:30:00 PM
Show Time As: Tentative

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 3/29/2019 1:55:25 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Dorjets, Vlad EOP/OMB
CC: Nickerson, William [Nickerson.William@epa.gov]

Ex. 6 Personal Privacy (PP)

Subject: Follow up on perchlorate

Location: call in Ex. 6 Personal Privacy (PP)

Start: 3/29/2019 5:00:00 PM

End: 3/29/2019 5:30:00 PM

Show Time As: Busy

Appointment

From: Dorjets, Vlad EOP/OMB; **Ex. 6 Personal Privacy (PP)**
Sent: 3/29/2019 1:57:36 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]

Subject: Accepted: Follow up on perchlorate
Location: call in **Ex. 6 Personal Privacy (PP)**

Start: 3/29/2019 5:00:00 PM
End: 3/29/2019 5:30:00 PM
Show Time As: Busy

Recurrence: (none)

Appointment

From: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]
Sent: 6/19/2017 2:56:08 PM
To: Hafez, Ahmed [Hafez.Ahmed@epa.gov]; Strong, Jamie [Strong.Jamie@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Grevatt, Peter [Grevatt.Peter@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Olson, Daniel [Olson.Daniel@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Schwab, Margo EOP/OMB
CC: **Ex. 6 Personal Privacy (PP)** Vlad Dorjets **Ex. 6 Personal Privacy (PP)**
Behl, Betsy [Behl.Betsy@epa.gov]; OP ADP Calendar [OP_ADP_Calendar@epa.gov]; Nurse, Leanne [Nurse.Leanne@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]
Subject: Perchlorate Peer Review Briefing with EPA
Location: **Ex. 6 Personal Privacy (PP)** access code **Ex. 6 Personal Privacy (PP)**
Start: 6/29/2017 7:00:00 PM
End: 6/29/2017 8:00:00 PM
Show Time As: Tentative

Message

From: Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]
Sent: 4/19/2019 4:57:56 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)] Burneson, Eric [Burneson.Eric@epa.gov]
CC: Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Huff, Lisa [Huff.Lisa@epa.gov]
Subject: RE: Proposed Perchlorate NPDWR
Attachments: Vol3 AppendixB-J BBDRModel_181114.docx; WA459_T3_Vol2 AppendixA BBDRModel_181113.docx; WA459_T4_Vol1 Main Report_181113.docx

Hi Vlad,

I just noticed that I inadvertently provided an earlier version of Volume I which Eric forwarded to you. Attached is a revised version of Volume 1 which incorporates minor editorial changes to the document. Sorry for the inconvenience.

Also, in response to your request I am attaching Volumes 2 and 3 of the Report.

Thanks
Sam

=====

Samuel Hernández Quiñones, P.E.
Environmental Engineer
Office of Water
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
202-564-1735

"USEPA Protecting Human Health and the Environment"

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Friday, April 19, 2019 12:01 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Eric/Lisa -- Could you please share Volumes II and III?

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Wednesday, April 17, 2019 4:23 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Vlad:

We can provide the requested support documents. The first document has been shared previously with many of the other Federal Agencies (see my email to Jim Kim on July 11, 2018) but we are happy to share this document again. It is attached to this email. The second document is currently under revision to incorporate some of the modifications we made just prior to submitting the proposed NPDWR. We expect to be able to send this document early next week.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>
Sent: Tuesday, April 16, 2019 3:54 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Eric,

Kevin Bromberg has apparently already skimmed (if not actually read) the NPRM and is requesting two documents referenced in the preamble: the “proposed approaches to inform the derivation of a maximum contaminant level goal for perchlorate in drinking water” (reference 2018d) and the TSD (reference 2018e). Could you please let me know the status of these two documents? In case they’re not currently available or will not be available soon it would help me to understand what they documents do and do not contain.

Vlad

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, April 16, 2019 1:10 PM
To: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: Proposed Perchlorate NPDWR

Vlad

Thanks for touching base regarding the perchlorate proposed drinking water regulation. As we discussed I have blocked time on April 25 at 3:00 pm for a briefing to the other Federal Agency’s on the perchlorate proposal. We will send an updated presentation to you early next week for distribution to the other Agency partners. I am assuming this will be a teleconference but let me know if you or other Federal partners would be interested in coming to EPA Offices for the meeting and I can book a larger room for the discussion.

As I mentioned I will be out of the office Thursday and Friday this week but if you have questions about the draft proposal you can contact Lisa Christ in my absence. Lisa’s number is 202 564 8354.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

Appointment

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: 5/16/2019 3:51:01 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]

Subject: Accepted: Hold for OMB call re Perchlorate
Location: EPA East 2331 A or **Ex. 6 Personal Privacy (PP)** code **Ex. 6 Personal Privacy (PP)**

Start: 5/22/2019 7:00:00 PM
End: 5/22/2019 8:00:00 PM
Show Time As: Busy

Recurrence: (none)

Appointment

From: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]
Sent: 6/16/2017 2:13:49 PM
To: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]; Hafez, Ahmed [Hafez.Ahmed@epa.gov]; Strong, Jamie [Strong.Jamie@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Grevatt, Peter [Grevatt.Peter@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Olson, Daniel [Olson.Daniel@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)] Vlad Dorjets [Ex. 6 Personal Privacy (PP)]
CC: Behl, Betsy [Behl.Betsy@epa.gov]; OP ADP Calendar [OP_ADP_Calendar@epa.gov]; Nurse, Leanne [Nurse.Leanne@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Flowers, Lynn [Flowers.Lynn@epa.gov]; Schlosser, Paul [Schlosser.Paul@epa.gov]; Huff, Lisa [Huff.Lisa@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; [Ex. 6 Personal Privacy (PP)]
Subject: Perchlorate Peer Review Briefing with EPA
Location: [Ex. 6 Personal Privacy (PP)], access code [Ex. 6 Personal Privacy (PP)]
Start: 6/29/2017 7:00:00 PM
End: 6/29/2017 8:00:00 PM
Show Time As: Busy

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 4/29/2019 9:29:32 PM
To: Jones, Lisa M. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: Accepted: E.O. 12866 MTG re: National Primary Drinking Water Regulations: Regulation of Perchlorate (RIN 2040-AF28)
Location: Room 9258, New Executive Office Building (NEOB)/OMB - 725 17th Street, NW, Washington, DC 20503
Start: 4/30/2019 8:00:00 PM
End: 4/30/2019 8:30:00 PM
Show Time As: Busy

Appointment

From: Burneson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cacb9a8d49f49af80531e9e2ccb9018-eburneso]
Sent: 5/28/2020 9:36:19 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]
Subject: Perchlorate
Location: Skype Meeting
Start: 6/1/2020 5:00:00 PM
End: 6/1/2020 6:00:00 PM
Show Time As: Busy

Join Skype Meeting

Trouble Joining? [Try Skype Web App](#)

Join by phone

Toll number: [Ex. 6 Personal Privacy (PP)] Dial-in Number English (United States)

[Find a local number](#)

Conference ID: [Ex. 6 Personal Privacy (PP)]

[Forgot your dial-in PIN?](#) | [Help](#)

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Thursday, May 28, 2020 12:26 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>
Subject: RE: Perchlorate

Let's go with 1:00 if that works for you and thanks for setting this up. And to be clear, this is just an informal chat to understand the thinking behind some of the decisions in the document. I don't plan to provide any comments at that time but simply ask a few questions to help inform my thinking as I prepare comments.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Thursday, May 28, 2020 12:22 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>
Subject: RE: Perchlorate

Vlad; I agree that it would be helpful to discuss the legal considerations involved in this action (including the timeline for clearing the action NLT June 17). I have checked with our General Counsel's Office representative and she is available at either 11am or 1 pm on Monday. Please let me know if you have a preference for either time and I can set up a meeting.
Eric

From: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>

Sent: Thursday, May 28, 2020 11:42 AM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Subject: Perchlorate

I imagine that a lot of what was drafted in the perchlorate rule is a result of very deliberate legal consideration. I think it would help me to understand whether [REDACTED] Ex. 5 Deliberative Process (DP)

[REDACTED] Ex. 5 Deliberative Process (DP) I expect to be done reading the document tomorrow (too many other things going on that prevent me from reading it straight through) so perhaps we could chat sometime on Monday?

Appointment

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/20/2019 6:19:08 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; eric.t.gormsen@usdoj.gov; Oakes, Matthew (ENRD) [Matthew.Oakes@usdoj.gov]; Eric.Hostetler@usdoj.gov; Nickerson, William [Nickerson.William@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]

Subject: EPA Perchlorate MCL NPRM
Location: Dial-in: [Ex. 6 Personal Privacy (PP)] Passcode: [Ex. 6 Personal Privacy (PP)]

Start: 5/20/2019 8:00:00 PM
End: 5/20/2019 8:30:00 PM
Show Time As: Busy

Recurrence: (none)

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 5/16/2019 3:41:34 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Vlad Dorjets [Ex. 6 Personal Privacy (PP)]
CC: Johnson, Ann [Johnson.Ann@epa.gov]
Subject: Hold for OMB call re Perchlorate
Location: EPA East 2331 A or [Ex. 6 Personal Privacy (PP)] code [Ex. 6 Personal Privacy (PP)]
Start: 5/21/2019 7:30:00 PM
End: 5/21/2019 8:30:00 PM
Show Time As: Busy

Due to some schedule changes I was just informed of regarding signature of this proposal we will need to have our discussion on Tuesday rather than Wednesday. Can we please hold this time for a follow up discussion?

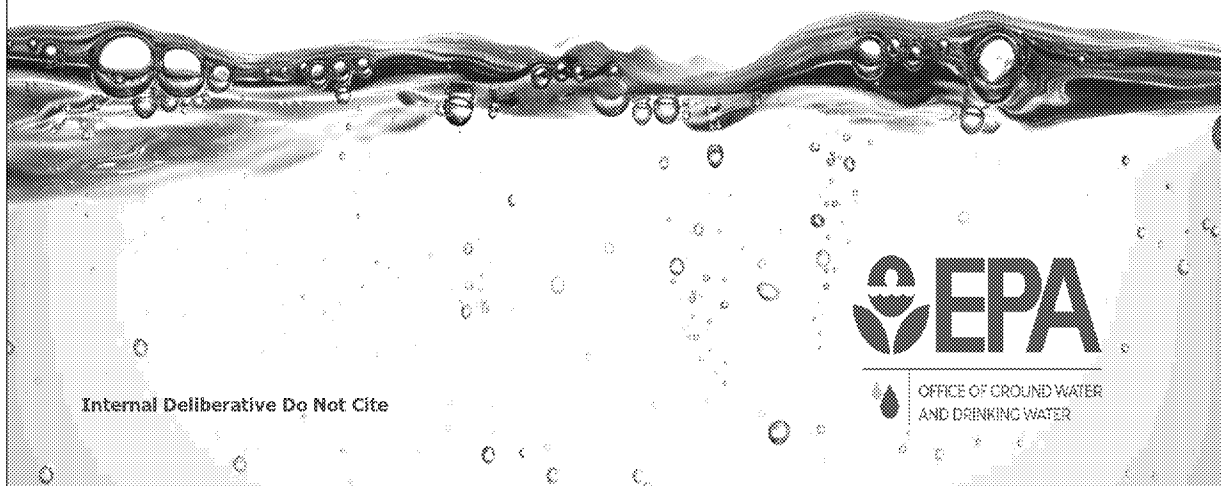
Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 4/16/2019 4:42:03 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]
CC: Johnson, Ann [Johnson.Ann@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Vladik_Dorjets [Ex. 6 Personal Privacy (PP)]
BCC: DCRoomEast2339/DC-ICC-OW-OGWDW [DCRoomEast2339@epa.gov]
Subject: Inter Agency Briefing on Proposed Perchlorate NPDWR
Attachments: Perchlorate Interagency Brief 4-25-19 V2.pptx
Location: DCRoomEast2339/DC-ICC-OW-OGWDW call in [Ex. 6 Personal Privacy (PP)] passcode [Ex. 6 Personal Privacy (PP)]
Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Busy

OMB has scheduled an Inter-Agency teleconference at this time for EPA to brief other Federal Agencies on the draft proposed drinking water regulation for perchlorate. EPA will deliver the attached slides and ask for any clarifying questions at the end.

Perchlorate Proposed Rule

April 2019



Internal Deliberative Do Not Cite



OFFICE OF GROUND WATER
AND DRINKING WATER

Regulatory History



- EPA included perchlorate on the 1st, 2nd, and 3rd Candidate Contaminant Lists (CCL); published 1998, 2005 and 2009.
- EPA included perchlorate in the 1st Unregulated Contaminant Monitoring Rule (UCMR1); data submitted 2001-2005.
 - 4.1% of water systems reported measurements greater than 4 µg/L (the minimum reporting level)
- 2008 preliminary Regulatory Determination.
 - Health Reference Level (HRL) of 15 µg/L based on reference dose of 0.7 µg/kg/day (NAS)
 - Decision to not regulate based on low occurrence at 15 µg/L
- 2009 supplemental request for comment on new analysis of derived alternative HRLs for 14 life stages.
 - Life-stage dependent HRLs ranging from 1 to 47 µg/L
- 2011 final Regulatory Determination
 - Decision to regulate based on meaningful opportunity to improve public health protection for 5 -16 million people served water containing perchlorate
 - SDWA required EPA to promulgate a proposed drinking water regulation by February 11, 2013, and a final rule by August 11, 2014.
- 2016 Lawsuit for failure to meet SDWA statutory deadlines for rule promulgation
 - Consent decree requires EPA to propose a drinking water regulation for Perchlorate no later than May 28, 2019, and finalize a rule by December 19, 2019.

Perchlorate Health Effects



- Perchlorate competes with iodide for transport through the sodium-iodide symporter (NIS) into the thyroid gland, which is a necessary step in the production of thyroid hormones Triiodothyronine (T3) and Thyroxine (T4) (NRC).
- Thyroid hormones are essential to the growth and development of fetuses, infants, and young children, as well as to metabolism and energy regulation throughout the lifespan (NRC).
- NRC evaluated the health implications of perchlorate ingestion at the request of EPA and other federal agencies in 2005. The committee concluded that hypothyroidism is the first adverse effect in the mode-of-action model. Any effects downstream of hypothyroidism clearly would be adverse. If perchlorate exposure did result in hypothyroidism, possible outcomes would be metabolic sequelae at any age and abnormal growth and development in fetuses or children (NRC).
- In 2013, EPA received input from SAB who concluded: To integrate the available information to develop a MCLG for perchlorate, the SAB urges the EPA to expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure. Incorporating these components into the model offers the opportunity for much greater scientific rigor in establishing quantitative relationships between perchlorate exposure and adverse effects at sensitive life stages.
- The association of maternal hypothyroxinemia with offspring neurodevelopment is supported by three meta-analyses (including one full systematic review), all of which conclude maternal hypothyroxinemia is associated with increased risk of cognitive delay, intellectual impairment, or lower scores on performance tests when considering the entire body of evidence on this topic (Fan & Wu, 2016; Thompson et al., 2018; Wang et al., 2016).
- The American Thyroid Association also concludes that "overall, available evidence appears to show an association between hypothyroxinemia and cognitive development of the offspring"

EPA Science Advisory Board Recommendations



- In 2012, EPA sought recommendations from the EPA Science Advisory Board (SAB) on how to use the RfD and proposed approach to derive an MCLG. The May 2013 SAB report recommended the following:
 - “derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling (PBPK);”
 - “expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure;”
 - “utilize an MOA framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition to thyroid hormone changes and finally neurodevelopmental impacts;”
 - “extend the [BBDR] model expeditiously to...provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages.”
- To address the SAB recommendations, EPA and FDA scientists worked collaboratively to develop models to predict the effects perchlorate exposure has on thyroid function in pregnant women and their children.

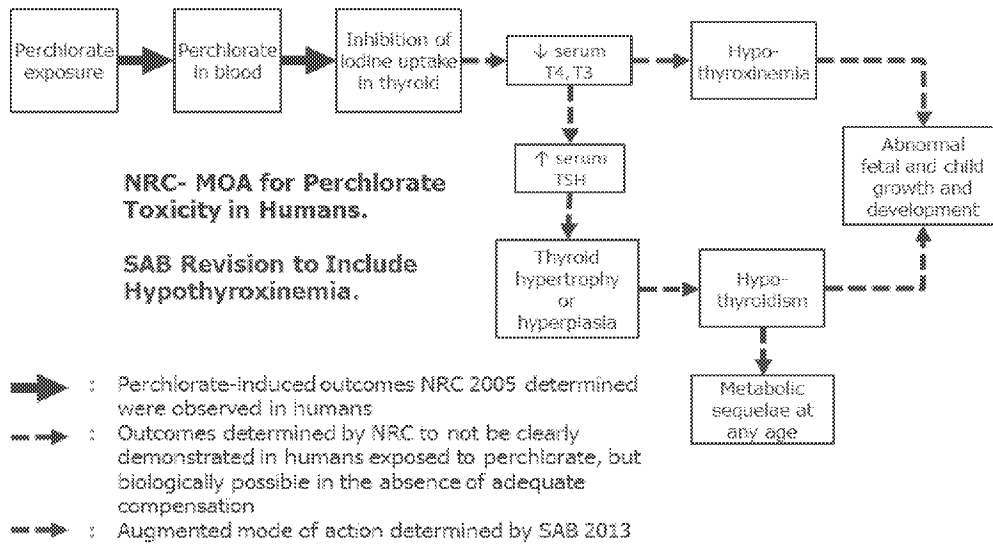
Internal Deliberative Do Not Cite

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“extend the [BBDR] model expeditiously to...provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages” (SAB, 2013, p. 19).

The SAB stated that EPA should more directly consider thyroid hormone changes as relevant to sensitive life stages; specifically, fetuses of hypothyroxinemic pregnant women and infants and neonates exposed to perchlorate through either water-based formula preparations or the breast milk of lactating women. This is because thyroid hormone deficiency is known to produce adverse effects on human neurodevelopment, an effect to which the above mentioned sensitive life stages are especially vulnerable. This direction is different from the conclusions of the NRC report, which based the RfD on the non-adverse effect of reduced iodide uptake and suggested examining pregnant women with hypothyroidism or iodide deficiency. The SAB approach focuses on the subtler changes in thyroid hormones (specifically fT4) associated with maternal hypothyroxinemia rather than broader changes in thyroid hormones (both fT4 and TSH) associated with hypothyroidism (Science Advisory Board (SAB), 2013, p. 25). Furthermore, the SAB recommended EPA consider available data on potential adverse health effects (i.e., neurodevelopmental outcomes) due to thyroid hormone level perturbations, regardless of the cause of those perturbations.

Perchlorate Mode of Action



MCLG Development - Overview

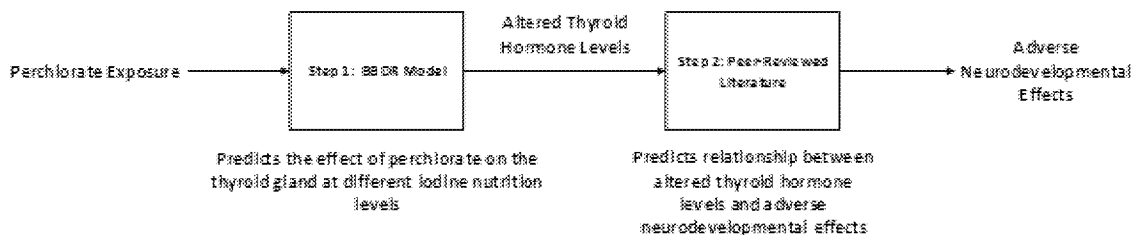


Two Step Analysis and Peer Review:

2017: EPA (with support of FDA) prepared and peer reviewed a BBDR model that predicts thyroid hormone changes that result from iodine nutrition and perchlorate exposure.

2018: EPA prepared and peer reviewed a revised BBDR model and a analysis of epidemiologic studies examining thyroid hormones changes in pregnant women to neurodevelopment effects.

"Overall, the committee agreed that the EPA and its collaborators have prepared a highly innovative state-of-the-science set of quantitative tools to evaluate neurodevelopmental effects that could arise from drinking water exposure to perchlorate. While there is always room for improvement of the models, with limited additional work to address the committee's comments below, the current models are fit-for-purpose to determine an MCLG."



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MCLG Development

Thyroid Hormone Changes and Neurodevelopment Impacts



Studies on Thyroid Hormone Changes and Neurodevelopment :

- Not every paper found a statistically significant association between maternal fT4 as a continuous variable (i.e., 5 of the initially identified 16 studies identified as potentially useful to inform a dose-response function) and the neurodevelopmental outcome of interest.
- However, several meta-analyses Fan & Wu, 2016; Thompson et al., 2018 and Wang et al., 2016, the American Thyroid Association (Alexander et al., 2017) and the U.S. EPA's SAB (2013) have concluded there is a relationship between maternal hypothyroxinemia and various neurodevelopmental outcomes.
- For derivation of the MCLG, EPA selected its reanalysis of the Korevaar study data based on the following factors:
 - 3600 mother-child data pairs,
 - Dose-response function for sensitive population of interest,
 - Able to control for confounders, and
 - Readily interpretable endpoint (IQ).

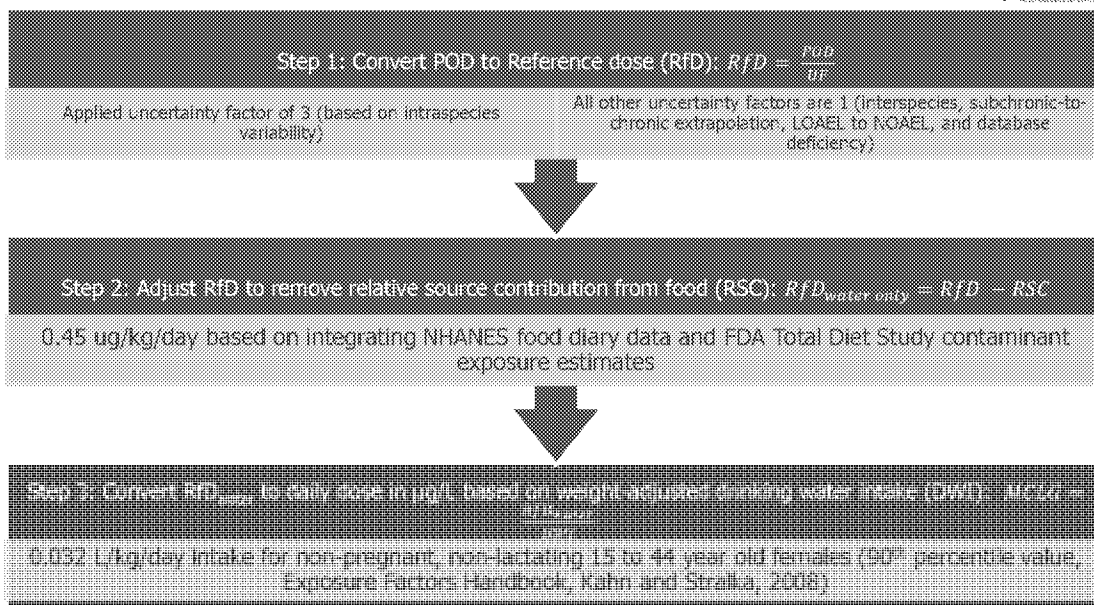
Point of Departure: Dose of perchlorate to result in a thyroid hormone change associated with:

1% change or 1-point IQ decrement (alternative):
POD=3.1
 $\mu\text{g/kg/day}$

2% change or 2-point IQ decrement:
POD=6.7
 $\mu\text{g/kg/day}$

3% change or 3-point IQ decrement (alternative):
POD=10.8
 $\mu\text{g/kg/day}$

POD to MCLG



Internal Deliberative Do Not Cite

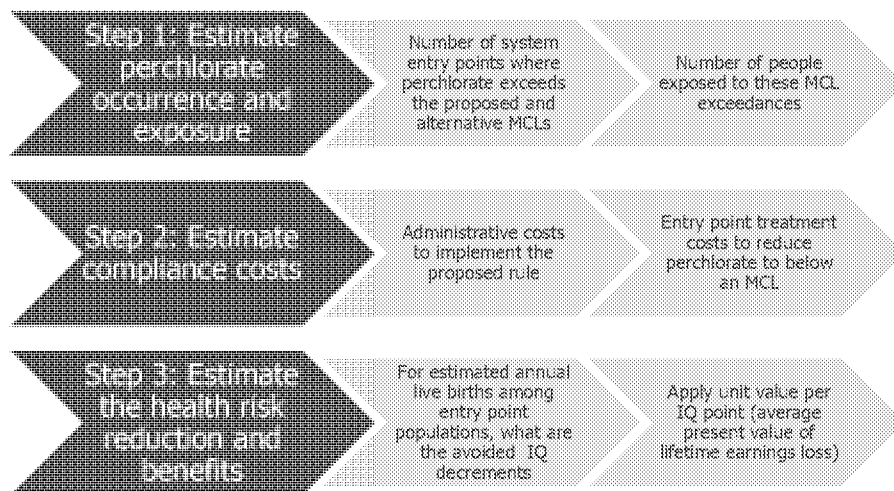
MCLG – Calculation



Item	1 IQ point decrement (alternative)	2 IQ point decrement	3 IQ point decrement (alternative)
POD	3.1 µg/kg/day	6.7 µg/kg/day	10.8 µg/kg/day
RfD = POD/UF	1.03 = 3.1/3	2.23 = 6.7/3	3.6 = 10.8/3
MCLG = (RfD-RSC)/DWI	18.13 = (1.03-0.45)/0.032	55.62 = (2.23-0.45)/0.032	90 = (3.6-0.45)/0.032
MCLG (rounded)	18 µg/L	56 µg/L	90 µg/L
Note: the RSC is the perchlorate dose (µg/kg/day) from food, not a percentage allocated to drinking water			

-
- **Ex. 5 Deliberative Process (DP)**

Benefit-Cost Analysis Method Overview



Internal Deliberative Do Not Cite


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Ex. 5 Deliberative Process (DP)

Cost Estimates



- -
 -
- Ex. 5 Deliberative Process (DP)**

- 
-
-
-

Benefit-Cost Analysis Summary



Ex. 5 Deliberative Process (DP)

Internal Deliberative Do Not Cite

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Proposed Rule and Alternatives



-
-
-

Ex. 5 Deliberative Process (DP)

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 3/29/2019 1:55:25 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
CC: Nickerson, William [Nickerson.William@epa.gov]
Subject: Follow up on perchlorate
Location: call in **Ex. 6 Personal Privacy (PP)** code **Ex. 6 Personal Privacy (PP)**
Start: 3/29/2019 5:00:00 PM
End: 3/29/2019 5:30:00 PM
Show Time As: Busy

Vlad:
Lets use my call in number above.

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: Friday, March 29, 2019 8:51 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: Re: Call tomorrow?

Either time works. Want me to call you at 1?

Sent from my iPhone

On Mar 28, 2019, at 6:26 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:

Vlad:
Do you have time for a call tomorrow between 1 and 2? If not then how about 2:30 or 3:30?

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

Appointment

From: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]
Sent: 6/16/2017 2:13:49 PM
To: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]; Hafez, Ahmed [Hafez.Ahmed@epa.gov]; Strong, Jamie [Strong.Jamie@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Grevatt, Peter [Grevatt.Peter@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Olson, Daniel [Olson.Daniel@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Vlad Dorjets [Ex. 6 Personal Privacy (PP)]; [Ex. 6 Personal Privacy (PP)]
CC: Behl, Betsy [Behl.Betsy@epa.gov]; OP ADP Calendar [OP_ADP_Calendar@epa.gov]; Nurse, Leanne [Nurse.Leanne@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Flowers, Lynn [Flowers.Lynn@epa.gov]; Schlosser, Paul [Schlosser.Paul@epa.gov]; Huff, Lisa [Huff.Lisa@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; James_H_Kim@ [Ex. 6 Personal Privacy (PP)]
Subject: Perchlorate Peer Review Briefing with EPA
Location: [Ex. 6 Personal Privacy (PP)], access code [Ex. 6 Personal Privacy (PP)]
Start: 6/29/2017 7:00:00 PM
End: 6/29/2017 8:00:00 PM
Show Time As: Busy

Use conference line [Ex. 6 Personal Privacy (PP)] and access code [Ex. 6 Personal Privacy (PP)]

Appointment

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 3/11/2019 5:12:16 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Burneson, Eric [Burneson.Eric@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Thomas, Amanda L. EOP/OMB [Ex. 6 Personal Privacy (PP)] Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Glass, Jacob S. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Theroux, Rich P. EOP/OMB [Ex. 6 Personal Privacy (PP)]

Subject: Perchlorate

Location: Dial-in: [Ex. 6 Personal Privacy (PP)] Passcode: [Ex. 6 Personal Privacy (PP)]

Start: 3/11/2019 8:00:00 PM

End: 3/11/2019 8:30:00 PM

Show Time As: Tentative

Recurrence: (none)

Appointment

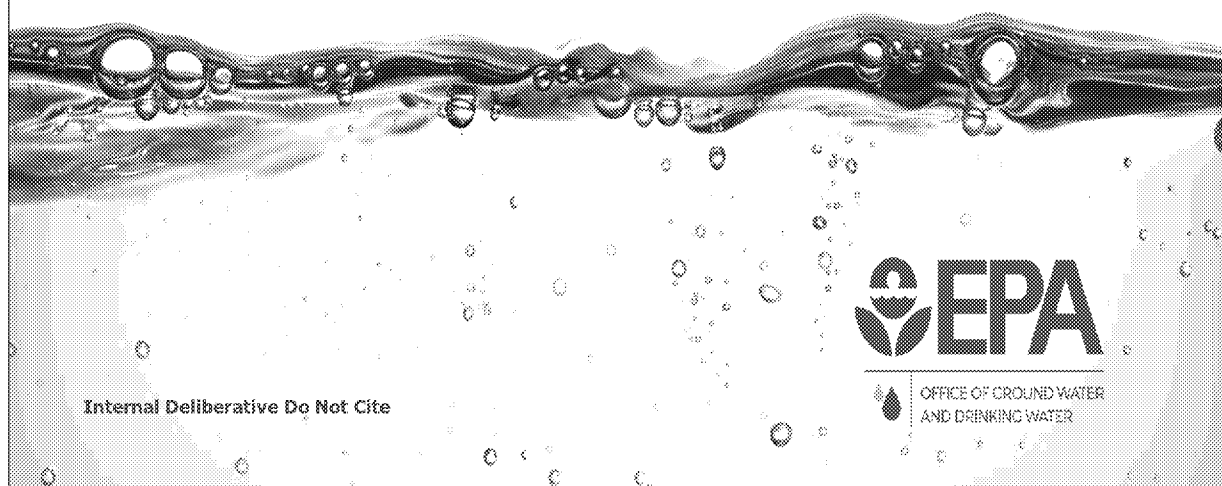
From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 3/5/2019 10:21:03 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Vlad Dorjets [Ex. 6 Personal Privacy (PP)]; [Ex. 6 Personal Privacy (PP)]; Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Johnson, Ann [Johnson.Ann@epa.gov]
BCC: DCRoomEast2418/DC-ICC-OW-OGWDW [DCRoomEast2418DC@epa.gov]
Subject: Perchlorate Proposed NPDWR
Attachments: Perchlorate Brief OMB 3-7-19_v3.pptx
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)] Conf [Ex. 6 Personal Privacy (PP)]
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Busy

Correction to the conference code ID

Pre Brief for OMB on the proposed perchlorate drinking water regulation.

Perchlorate Proposed Rule

March 7, 2019



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OFFICE OF GROUND WATER
AND DRINKING WATER

Regulatory History



- EPA included perchlorate on the 1st, 2nd, and 3rd Candidate Contaminant Lists (CCL); published 1998, 2005 and 2009.
- EPA included perchlorate in the 1st Unregulated Contaminant Monitoring Rule (UCMR1); data submitted 2001-2005.
 - 4.1% of water systems reported measurements greater than 4 µg/L (the minimum reporting level)
- 2008 preliminary Regulatory Determination.
 - Health Reference Level (HRL) of 15 µg/L based on reference dose of 0.7 µg/kg/day (NAS)
 - Decision to not regulate based on low occurrence at 15 µg/L
- 2009 supplemental request for comment on new analysis of derived alternative HRLs for 14 life stages.
 - Life-stage dependent HRLs ranging from 1 to 47 µg/L
- 2011 final Regulatory Determination
 - Decision to regulate based on meaningful opportunity to improve public health protection for 5 -16 million people served water containing perchlorate
 - SDWA required EPA to promulgate a proposed drinking water regulation by February 11, 2013, and a final rule by August 11, 2014.
- 2016 Lawsuit for failure to meet SDWA statutory deadlines for rule promulgation
 - Consent decree requires EPA to propose a drinking water regulation for Perchlorate no later than May 28, 2019, and finalize a rule by December 19, 2019.

Perchlorate Health Effects



- Perchlorate competes with iodide for transport through the sodium-iodide symporter (NIS) into the thyroid gland, which is a necessary step in the production of thyroid hormones Triiodothyronine (T3) and Thyroxine (T4) (NRC).
- Thyroid hormones are essential to the growth and development of fetuses, infants, and young children, as well as to metabolism and energy regulation throughout the lifespan (NRC).
- NRC evaluated the health implications of perchlorate ingestion at the request of EPA and other federal agencies in 2005. The committee concluded that hypothyroidism is the first adverse effect in the mode-of-action model. Any effects downstream of hypothyroidism clearly would be adverse. If perchlorate exposure did result in hypothyroidism, possible outcomes would be metabolic sequelae at any age and abnormal growth and development in fetuses or children (NRC).
- In 2013, EPA received input from SAB who concluded: To integrate the available information to develop a MCLG for perchlorate, the SAB urges the EPA to expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure. Incorporating these components into the model offers the opportunity for much greater scientific rigor in establishing quantitative relationships between perchlorate exposure and adverse effects at sensitive life stages.
- The association of maternal hypothyroxinemia with offspring neurodevelopment is supported by three meta-analyses (including one full systematic review), all of which conclude maternal hypothyroxinemia is associated with increased risk of cognitive delay, intellectual impairment, or lower scores on performance tests when considering the entire body of evidence on this topic (Fan & Wu, 2016; Thompson et al., 2018; Wang et al., 2016).
- The American Thyroid Association also concludes that "overall, available evidence appears to show an association between hypothyroxinemia and cognitive development of the offspring"

EPA Science Advisory Board Recommendations



- In 2012, EPA sought recommendations from the EPA Science Advisory Board (SAB) on how to use the RfD and proposed approach to derive an MCLG. The May 2013 SAB report recommended the following:
 - “derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling (PBPK);”
 - “expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure;”
 - “utilize an MOA framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition to thyroid hormone changes and finally neurodevelopmental impacts;”
 - “extend the [BBDR] model expeditiously to...provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages.”
- To address the SAB recommendations, EPA and FDA scientists worked collaboratively to develop models to predict the effects perchlorate exposure has on thyroid function in pregnant women and their children.

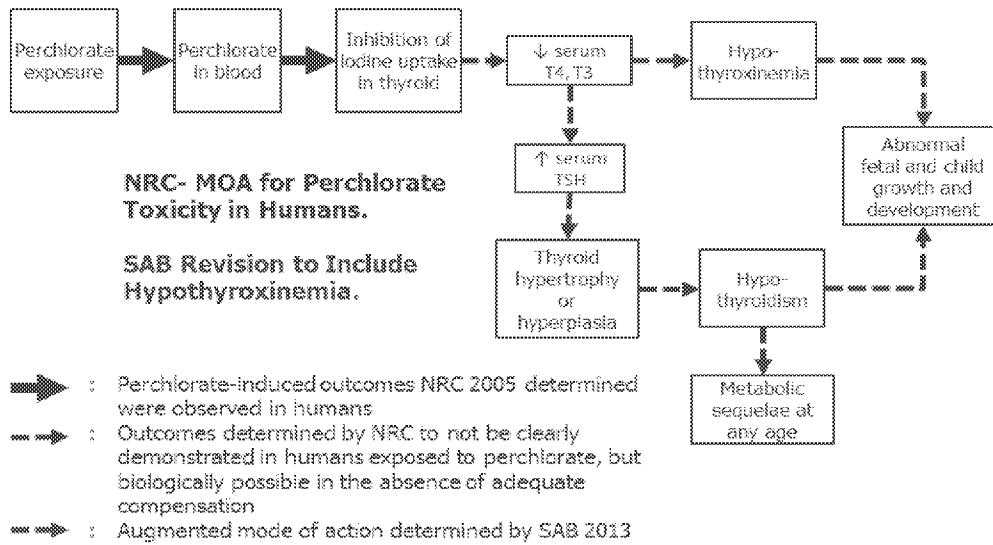
Internal Deliberative Do Not Cite

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“extend the [BBDR] model expeditiously to...provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages” (SAB, 2013, p. 19).

The SAB stated that EPA should more directly consider thyroid hormone changes as relevant to sensitive life stages; specifically, fetuses of hypothyroxinemic pregnant women and infants and neonates exposed to perchlorate through either water-based formula preparations or the breast milk of lactating women. This is because thyroid hormone deficiency is known to produce adverse effects on human neurodevelopment, an effect to which the above mentioned sensitive life stages are especially vulnerable. This direction is different from the conclusions of the NRC report, which based the RfD on the non-adverse effect of reduced iodide uptake and suggested examining pregnant women with hypothyroidism or iodide deficiency. The SAB approach focuses on the subtler changes in thyroid hormones (specifically fT4) associated with maternal hypothyroxinemia rather than broader changes in thyroid hormones (both fT4 and TSH) associated with hypothyroidism (Science Advisory Board (SAB), 2013, p. 25). Furthermore, the SAB recommended EPA consider available data on potential adverse health effects (i.e., neurodevelopmental outcomes) due to thyroid hormone level perturbations, regardless of the cause of those perturbations.

Perchlorate Mode of Action



MCLG Development - Overview

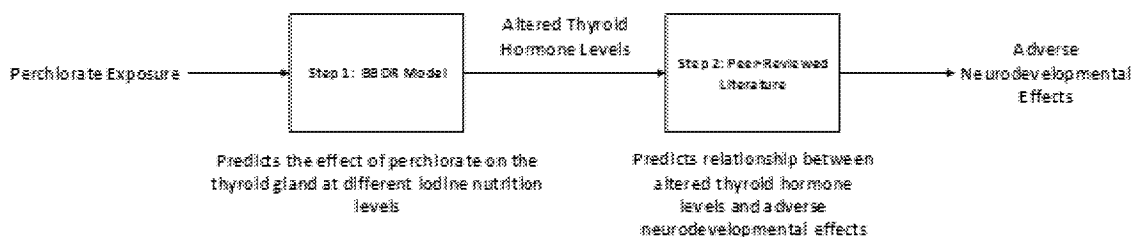


Two Step Analysis and Peer Review:

2017: EPA (with support of FDA) prepared and peer reviewed a BBDR model that predicts thyroid hormone changes that result from iodine nutrition and perchlorate exposure.

2018: EPA prepared and peer reviewed a revised BBDR model and a analysis of epidemiologic studies examining thyroid hormones changes in pregnant women to neurodevelopment effects.

"Overall, the committee agreed that the EPA and its collaborators have prepared a highly innovative state-of-the-science set of quantitative tools to evaluate neurodevelopmental effects that could arise from drinking water exposure to perchlorate. While there is always room for improvement of the models, with limited additional work to address the committee's comments below, the current models are fit-for-purpose to determine an MCLG."



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Thyroid Hormone Changes and Neurodevelopment Impacts



2013 SAB Report:

"The mode of action involves the potential to disturb thyroid homeostasis by limiting the iodide uptake by the thyroid, which in turn can lead to production of less thyroid hormone. Interference with the thyroid and available thyroid hormones is known to produce adverse effects on neurodevelopment in humans, with fetuses and infants being most vulnerable. Although adverse neurodevelopmental effects of perchlorate in infants and children have not been reported in the literature, the risk of adverse effects can be reasonably inferred from perchlorate's mode of action and the known role of thyroid hormone on human brain development."

Recent Studies:

Decrease in thyroid hormone levels during pregnancy, especially into the hypothyroxinemic range, have been linked to many adverse neurodevelopmental outcomes in offspring, including IQ decrements, schizophrenia, ADHD, expressive language delay, reduced school performance, autism, and delayed cognitive development.

For derivation of the MCLG, EPA selected its reanalysis of the Korevaar study data based on the following factors:

- 3600 mother-child data pairs,
- Dose-response function for sensitive population of interest,
- Able to control for confounders, and
- Readily interpretable endpoint (IQ).

Proposed MCLG – Dose-Response Function

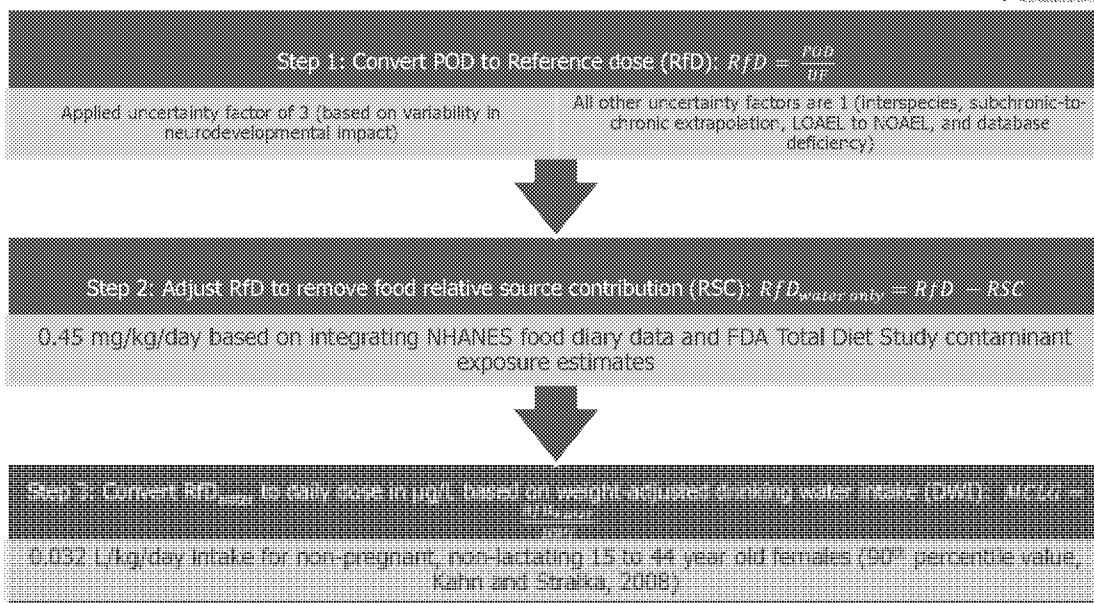


Point of Departure: thyroid hormone change associated with:

2% change or 2-point IQ decrement:
RfD=6.7 $\mu\text{g/kg/day}$

1% change or 1-point IQ decrement (alternative):
RfD=3.1 $\mu\text{g/kg/day}$

POD to MCLG



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MCLG – Alternatives



Item	2 IQ point decrement	1 IQ point decrement
POD	6.7 µg/kg/day	3.1 µg/kg/day
RfD = POD/UF	2.23 = 6.7/3	1.03 = 3.1/3
MCLG = (RfD-RSC)/DWI	55.62 = (2.23- 0.45)/0.032	18.13 = (1.03- 0.45)/0.032
MCLG (rounded)	56 µg/L	18 µg/L
Note: the RSC is perchlorate µg/kg/L from food, not a percentage allocated to drinking water		

-
- **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

Estimate Costs

-
-

Ex. 5 Deliberative Process (DP)

Benefit-Cost Analysis Method Overview



Estimate Benefits

- For CWS that treat to reduce perchlorate to below the MCL
 - Estimate change IQ decrements from baseline perchlorate to treatment target (80% x MCL)
 - BBDR-based dose-response functions that translate baseline and policy perchlorate concentrations into two fT4 levels: $fT4_{i,p} = \beta_i \times P_p + I_i$, where beta and intercept values vary for 15 iodine intake levels
 - Epidemiological function that translates changes in fT4 into change in IQ $\Delta IQ = (\gamma \times \ln(fT4_i)) - (\gamma \times \ln(fT4_0))$ (gamma = coefficient from Korevaar reanalysis 17.26 (3.77, 30.75))
 - Multiply \$/IQ value from lead dust rule by aggregate changes in IQ over all affected entry points.

Benefits and costs reported for UCMR1 sample and extrapolated to national estimates using UCMR sampling weights and observed exceedance rate.

Ex. 5 Deliberative Process (DP)

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For either MCL, the costs exceed the benefits by a factor of 4 to 30. Thus, net benefits are negative. Incremental net benefits from 56 to 18 are also negative.

Proposed Rule and Alternatives



- -
 -
- Ex. 5 Deliberative Process (DP)**

Appointment

From: Burneson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cacb9a8d49f49af80531e9e2ccb9018-eburneso]
Sent: 6/5/2020 4:07:05 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]
Subject: EO12866: OMB Comments on Perchlorate Notice
Location: Skype Meeting
Start: 6/5/2020 7:30:00 PM
End: 6/5/2020 8:00:00 PM
Show Time As: Busy

Vlad can we discuss two topics regarding the comments on the perchlorate notice?

: **Ex. 5 Deliberative Process (DP)**

→ [Join Skype Meeting](#)

Trouble Joining? [Try Skype Web App](#)

Join by phone

Toll number: [Ex. 6 Personal Privacy (PP)] access code: [Ex. 6 Personal Privacy (PP)] Dial-in Number) English (United States)

[Find a local number](#)

Conference ID: [Ex. 6 Personal Privacy (PP)] (same as access code above)

[Forgot your dial-in PIN?](#) | [Help](#)

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]

Sent: Friday, June 05, 2020 10:07 AM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>;

Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks and that works. Note that I have just gotten off the phone with DOJ regarding whether this notice is

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) I am not ready to offer any recommendation on **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

of course, SBA just issued a public letter in the context of the MSGP pushing back on that approach but I may be able to

Ex. 5 Deliberative Process (DP)

We can discuss further later today or next week.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Friday, June 5, 2020 9:15 AM

To: Dorjets, Vlad EOP/OMB Ex. 6 Personal Privacy (PP)

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>;

Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad

We received this additional set of EOP comment and we will fold this in with the OMB, SBA and USDA comments. I assume your deadline for inter agency comments was yesterday and there should be no more comments forthcoming. Regarding this afternoon, I am not certain if we need a conversation at this stage as we are still evaluating the comments, but I would like to put a placeholder on your calendar for 3:30 just in case it is needed. I will follow up later this morning to confirm and let you know what if any topics we want to discuss. Does that work?

From: Dorjets, Vlad EOP/OMB Ex. 6 Personal Privacy (PP)

Sent: Friday, June 05, 2020 8:58 AM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>;

Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks for combining the comments. Unfortunately, I need to throw another curve ball because I received some late comments from an EOP reviewer that I have to pass on. They are attached. You will find that many are technical/stylistic but there are also a couple legal questions. I would appreciate it if you could incorporate these comments and responses into your master passback as well.

Sorry again for the piecemeal submission of comments. Hopefully, it's not a huge inconvenience for you and, if anything, has saved more time than it has cost.

As for chatting, I may have a little time after the EO meeting but I have an EO meeting on another rule at 3:00. We can play by ear but I'm happy to pencil in a chat at 2:30? Would just be me and you (in which case one of us can just call the other) or a broader group requiring a conference line? If we don't have enough time, I'm completely free after 3:00 meeting so would be happy pick think up at, say, 3:30 or 4:00.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Friday, June 5, 2020 8:33 AM

To: Dorjets, Vlad EOP/OMB Ex. 6 Personal Privacy (PP)

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>;

Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad: We have combined the three comment documents into a single file and will prepare a passback with this combined file. Are you available after the 12866 meeting with AWWA this afternoon in case we have any questions about the comments?

From: Dorjets, Vlad EOP/OMB [mailto:Ex. 6 Personal Privacy (PP)]

Sent: Thursday, June 04, 2020 6:05 PM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Really sorry but it looks like I jumped the gun more than I had realized; I just received comments from SBA which I wasn't expecting. I'm not sure I agree with all of SBA's comments so, perhaps, once you've reviewed these and other comments we can chat briefly about options. Hopefully these are the last of the comments.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:05 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: 'Parikh, Pooja' <Parikh.Pooja@epa.gov>; 'Christ, Lisa' <Christ.Lisa@epa.gov>; 'Johnson, Ann' <Johnson.Ann@epa.gov>; 'Wehling, Carrie' <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Murphy's Law is alive and well. Just as I clicked send on the message below, I received the attached comments from USDA. Having heard from all the agencies I knew may be interested in perchlorate (DOD, HHS/FDA, NASA, SBA), I did not expect anybody else to submit comments. I would appreciate it if you could incorporate these comments and your responses to them into your passback.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:00 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Vlad

Appointment

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 6/2/2020 6:14:00 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Burneson, Eric [Burneson.Eric@epa.gov]; Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]

Subject: Call w/ DOJ re Perchlorate

Location: [Ex. 6 Personal Privacy (PP)]

Start: 6/4/2020 8:00:00 PM

End: 6/4/2020 9:00:00 PM

Show Time As: Busy

Recurrence: (none)

Appointment

From: Martin, Italy M. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/29/2020 4:44:40 PM
To: Martin, Italy M. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Kymn, Christine J. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Kluever, April N. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Grossman, Andrea L. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Varcoe, Andrew R. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Troutman, Joel D. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Brooke, Francis J. Jr. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Malpass, Robert H. EOP/WHO [Ex. 6 Personal Privacy (PP)]; DL CEQ RegReview [Ex. 6 Personal Privacy (PP)]; Hickey, Jonathan P. EOP/OVP [Ex. 6 Personal Privacy (PP)]; Sidler, Matthew R. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Burneson, Eric [Burneson.Eric@epa.gov]; Parikh, Pooja [Parikh.Pooja@epa.gov]

Subject: E.O. 12866 Meeting 2040-AF28 - National Primary Drinking Water Regulations: Regulation of Perchlorate
Location: TELCONFERENCE

Start: 6/5/2020 6:00:00 PM
End: 6/5/2020 6:30:00 PM
Show Time As: Busy

Recurrence: (none)

This meeting was requested by: **American Water Works Association**

Client Name: **Kevin Morley**

Email: kmorley@awwa.org Phone: 202-326-6124

Call-in: [Ex. 6 Personal Privacy (PP)] Conference ID: [Ex. 6 Personal Privacy (PP)]

Appointment

Sent: 6/2/2020 5:14:57 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)] Wehling, Carrie [Wehling.Carrie@epa.gov]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]
Subject: Perchlorate Question

Start: 6/4/2020 4:30:00 PM
End: 6/4/2020 5:00:00 PM
Show Time As: Busy

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Tuesday, June 02, 2020 1:05 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Perchlorate Question

Thanks for the quick response. That's what I thought you were doing but there are a couple places where I think the point is a little muddles so I will try to offer some minor tweaks.

Also, I just heard from DOJ and they have comments they would like to convey by phone. They are available Thursday after 11:00 a.m. (they also provided availability for Friday and Monday and Tuesday of next week but I think you would agree that the sooner we have this call the better). I have calls at 1:30 and 3:30 that I'd prefer to be on but can miss if necessary so can be pretty flexible that day. Could you please let me know availability on your end and I'll set up the call?

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, June 2, 2020 12:58 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Perchlorate Question

Vlad;

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

We are stating that

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Based on that new

information, we have

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency

From: Dorjets, Vlad EOP/OMB <[REDACTED]> **Ex. 6 Personal Privacy (PP)**
Sent: Tuesday, June 02, 2020 12:22 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>
Subject: Perchlorate Question

Eric,

I am re-reading the perchlorate notice and was hoping you could clarify one more thing for me. Is EPA saying that the

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) ? Or perhaps some combination of the two? This point is a bit muddled so it would help me understand your intention before I try to suggest edits.

Thanks,

Vlad

Appointment

From: Jones, Lisa M. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 4/23/2019 8:39:02 PM
To: Jones, Lisa M. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Mancini, Dominic J. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Theroux, Rich P. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Thomas, Amanda L. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Kluever, April N. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Glass, Jacob S. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Falk Curtin, Edna T. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Nickerson, William [Nickerson.William@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]

Subject: E.O. 12866 MTG re: National Primary Drinking Water Regulations: Regulation of Perchlorate (RIN 2040-AF28)
Location: Room 9258, New Executive Office Building (NEOB)/OMB - 725 17th Street, NW, Washington, DC 20503

Start: 4/30/2019 8:00:00 PM
End: 4/30/2019 8:30:00 PM
Show Time As: Busy

Recurrence: (none)

This meeting was requested by the American Water Works Association.

Call-in: [Ex. 6 Personal Privacy (PP)] code [Ex. 6 Personal Privacy (PP)]

Here's the link for security information needed and the link may be shared: [Ex. 6 Personal Privacy (PP)]

Please include name as it shows exactly on driver's license or other government-issued identification to be used. Thank you.

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 5/16/2019 3:41:34 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Vlad Dorjets **Ex. 6 Personal Privacy (PP)** **Ex. 6 Personal Privacy (PP)**
Subject: Hold for OMB call re Perchlorate
Location: EPA East 2331 A or **Ex. 6 Personal Privacy (PP)** code **Ex. 6 Personal Privacy (PP)**
Start: 5/21/2019 7:30:00 PM
End: 5/21/2019 8:30:00 PM
Show Time As: Busy

Due to some schedule changes I was just informed of regarding signature of this proposal we will need to have our discussion on Tuesday rather than Wednesday. Can we please hold this time for a follow up discussion?

Message

From: Kluever, April [April.Kluever@fda.hhs.gov]
Sent: 7/21/2017 7:05:41 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; James_H_Kim [Ex. 6 Personal Privacy (PP)]
CC: Abt, Eileen [Eileen.Abt@fda.hhs.gov]; Kabadi, Shruti [Shruti.Kabadi@fda.hhs.gov]; Dinovi, Michael J [Michael.Dinovi@fda.hhs.gov]; Suzanne_Fitzpatrick [Suzanne.Fitzpatrick@fda.hhs.gov]
Subject: FDA/CFSAN review of EPA charge questions
Attachments: DRAFT MCLG Approach Charge 06-01-17 Combined CFSAN comments.docx

Hi Eric and Jim,

Please find the combined comments from FDA/CFSAN on the EPA charge questions for the 2nd perchlorate peer review. Thank you for the opportunity to comment on the charge and questions.

Thank you,

April

April Neal Kluever, Ph.D., D.A.B.T.
Toxicologist

Center for Food Safety and Applied Nutrition (CFSAN)
Office of Food Additive Safety (OFAS)
Division of Food Contact Notifications (DFCN)
U.S. Food and Drug Administration
5001 Campus Drive, HFS 275
College Park, MD 20740
Tel: 240-402-1225
April.kluever@fda.hhs.gov



Message

From: Dorjets, Vlad EOP/OMB
Sent: 6/10/2020 6:07:04 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]
Subject: RE: EO12866: OMB Comments on Perchlorate Notice
Attachments: EO12866 EPA Perchlorate Rule (OMB 06-10-20 Prelim).docx

Eric,

Thanks again for addressing comments so quickly. Please note that I have not heard from all reviewers yet (I gave them until COB Thursday to get back to me) so the attached comments should be seen as provisional. That being said, I have heard back from SBA so wanted to go ahead and pass along their comments to you. I have clearly identified the follow-up comments submitted by SBA in the attached documents. Most are worded as helpful suggestions but let me know if you have any concerns. Also, I have fixed a number of typos but you may want to give the document a careful scrub as part of a final review. I realize that, by sending this document, I have created some version control challenges but I felt it was important to pass along SBA's comments now.

Feel free to give me a call if you want to discuss.

Vlad

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, June 9, 2020 5:41 PM
To: Dorjets, Vlad EOP/OMB
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad;

Attached please find EPA's edits and responses to the consolidated comments received from the Inter Agency Review. We have accepted the majority of recommended edits and have offered alternative language where appropriate.

As we discussed DOJ has requested signature of this action not later than June 18, 2020. We therefore need OMB clearance by June 17.

We can meet to discuss any questions you have regarding the attached document. Thank you for your coordination and your input on this important action.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Friday, June 05, 2020 10:07 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks and that works. Note that I have just gotten off the phone with DOJ regarding whether this notice is [Ex. 5 Deliberative Process (DP)]
[Ex. 5 Deliberative Process (DP)]
[Ex. 5 Deliberative Process (DP)] I am not ready to offer any recommendation on [Ex. 5 Deliberative Process (DP)]
Ex. 5 Deliberative Process (DP) of
course, SBA just issued a public letter in the context of the MSGP pushing back on that approach but I may be able to convince them to [Ex. 5 Deliberative Process (DP)]
[Ex. 5 Deliberative Process (DP)] We can discuss further later today or next week.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Friday, June 5, 2020 9:15 AM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad
We received this additional set of EOP comment and we will fold this in with the OMB, SBA and USDA comments. I assume your deadline for inter agency comments was yesterday and there should be no more comments forthcoming. Regarding this afternoon, I am not certain if we need a conversation at this stage as we are still evaluating the comments, but I would like to put a placeholder on your calendar for 3:30 just in case it is needed. I will follow up later this morning to confirm and let you know what if any topics we want to discuss. Does that work?

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Friday, June 05, 2020 8:58 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks for combining the comments. Unfortunately, I need to throw another curve ball because I received some late comments from an EOP reviewer that I have to pass on. They are attached. You will find that many are technical/stylistic but there are also a couple legal questions. I would appreciate it if you could incorporate these comments and responses into your master passback as well.

Sorry again for the piecemeal submission of comments. Hopefully, it's not a huge inconvenience for you and, if anything, has saved more time than it has cost.

As for chatting, I may have a little time after the EO meeting but I have an EO meeting on another rule at 3:00. We can play by ear but I'm happy to pencil in a chat at 2:30? Would just be me and you (in which case one of us can just call the other) or a broader group requiring a conference line? If we don't have enough time, I'm completely free after 3:00 meeting so would be happy pick think up at, say, 3:30 or 4:00.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Friday, June 5, 2020 8:33 AM

To: Dorjets, Vlad EOP/OMB <[REDACTED]> **Ex. 6 Personal Privacy (PP)**

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad: We have combined the three comment documents into a single file and will prepare a passback with this combined file. Are you available after the 12866 meeting with AWWA this afternoon in case we have any questions about the comments?

From: Dorjets, Vlad EOP/OMB <[REDACTED]> **Ex. 6 Personal Privacy (PP)**

Sent: Thursday, June 04, 2020 6:05 PM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Really sorry but it looks like I jumped the gun more than I had realized; I just received comments from SBA which I wasn't expecting. I'm not sure I agree with all of SBA's comments so, perhaps, once you've reviewed these and other comments we can chat briefly about options. Hopefully these are the last of the comments.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:05 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: 'Parikh, Pooja' <Parikh.Pooja@epa.gov>; 'Christ, Lisa' <Christ.Lisa@epa.gov>; 'Johnson, Ann' <Johnson.Ann@epa.gov>; 'Wehling, Carrie' <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Murphy's Law is alive and well. Just as I clicked send on the message below, I received the attached comments from USDA. Having heard from all the agencies I knew may be interested in perchlorate (DOD, HHS/FDA, NASA, SBA), I did not expect anybody else to submit comments. I would appreciate it if you could incorporate these comments and your responses to them into your passback.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:00 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Vlad

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 7/20/2017 10:14:31 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Automatic reply: Perchlorate Follow up

I will be out of the office the week of July 21 with limited access to email. If you need assistance during that time please contact Jim Laity at

[Ex. 6 Personal Privacy (PP)]

or Aaron Szabo at

[Ex. 6 Personal Privacy (PP)]

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 8/6/2017 1:30:19 PM
To: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]
CC: Burneson, Eric [Burneson.Eric@epa.gov]; James_H_Kim@[Ex. 6 Personal Privacy (PP)]
Subject: Re: Interagency briefing on Perchlorate Peer Review hosted by EPA

Caryn - I had to go up to Boston for a family early matter so Jim Kim (copied) will send you our comments on the charge questions by COB tomorrow. I should be back in the office on Tuesday and will keep an eye on email tomorrow. On a separate note, you should have received note from Lisa August, the new NASA RMO, who needs to attend Wednesday's briefing.

Sent from my iPhone

On Aug 4, 2017, at 10:12 AM, Muellerleile, Caryn
<Muellerleile.Caryn@epa.gov<mailto:Muellerleile.Caryn@epa.gov>> wrote:

Thank you for your input on our charge for the peer review of methodologies to inform a perchlorate MCLG. We have continued to work on our characterization of the analysis and to improve the charge questions for the peer reviewers. We have planned an additional discussion with you for Wednesday August 9, to share more information and answer your questions about the draft analysis.

Please respond to me, Eric Burneson and Vlad Dorjets with the key issues or questions you would like us to address in the meeting on Wednesday so that we can be better prepared to discuss those concerns. We continue to consider the thoughtful input you have provided on the charge to this point and are preparing a revised charge for your consideration and comment. We will distribute the revised charge prior to the meeting.

Caryn Muellerleile
Regulatory Management Division
Office of Policy
US Environmental Protection Agency
1200 Pennsylvania Ave NW (1803A)
Washington, DC 20460
(202) 564-2855
muellerleile.caryn@epa.gov<mailto:muellerleile.caryn@epa.gov>

Message

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: 6/4/2020 10:04:41 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]
Subject: RE: EO12866: OMB Comments on Perchlorate Notice
Attachments: EO12866 EPA Perchlorate Rule (SBA).docx

Really sorry but it looks like I jumped the gun more than I had realized; I just received comments from SBA which I wasn't expecting. I'm not sure I agree with all of SBA's comments so, perhaps, once you've reviewed these and other comments we can chat briefly about options. Hopefully these are the last of the comments.

From: Dorjets, Vlad EOP/OMB
Sent: Thursday, June 4, 2020 5:05 PM
To: 'Burneson, Eric' <Burneson.Eric@epa.gov>
Cc: 'Parikh, Pooja' <Parikh.Pooja@epa.gov>; 'Christ, Lisa' <Christ.Lisa@epa.gov>; 'Johnson, Ann' <Johnson.Ann@epa.gov>; 'Wehling, Carrie' <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Murphy's Law is alive and well. Just as I clicked send on the message below, I received the attached comments from USDA. Having heard from all the agencies I knew may be interested in perchlorate (DOD, HHS/FDA, NASA, SBA), I did not expect anybody else to submit comments. I would appreciate it if you could incorporate these comments and your responses to them into your passback.

From: Dorjets, Vlad EOP/OMB
Sent: Thursday, June 4, 2020 5:00 PM
To: 'Burneson, Eric' <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to **Ex. 5 Deliberative Process (DP)**
Ex. 5 Deliberative Process (DP) I'm sure you can guess where my office would stand on the matter.

Vlad

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 7/10/2017 5:52:58 PM
To: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: James_H_Kim@[Ex. 6 Personal Privacy (PP)] Burneson, Eric [Burneson.Eric@epa.gov]
Subject: RE: briefings on OW actions

Yes, please go ahead and send the invite. In the invite, can you please include the agenda and the links below to make it easier for reviewers when I forward it to them? Also, can you please attach the briefing material and draft charge questions? Thanks!

From: Muellerleile, Caryn [mailto:Muellerleile.Caryn@epa.gov]
Sent: Monday, July 10, 2017 1:29 PM
To: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: briefings on OW actions

I can send an invite for Tuesday if that works for you, Vlad.

Another docket for the perchlorate peer review model materials: <https://www.regulations.gov/docket?D=EPA-HQ-OW-2016-0439>

From: Schwab, Margo EOP/OMB [mailto: [Ex. 6 Personal Privacy (PP)]]
Sent: Monday, July 10, 2017 12:08 PM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: James_H_Kim@[Ex. 6 Personal Privacy (PP)] Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: briefings on OW actions

My preference is for Tuesday

From: Muellerleile, Caryn [mailto:Muellerleile.Caryn@epa.gov]
Sent: Monday, July 10, 2017 11:13 AM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: briefings on OW actions

Hello,

Just checking in to see if you have a preference for meeting dates: next Tues 7/18 at 2 p.m. or Wed. 7/19 at 3 p.m.?

Also, the draft BBDR model that EPA released last year and subsequent public comments are all available at:
<https://www.regulations.gov/docket?D=EPA-HQ-OW-2016-0438>

thank you,
Caryn

Caryn Muellerleile

Regulatory Management Division
Office of Policy
US Environmental Protection Agency
1200 Pennsylvania Ave NW (1803A)
Washington, DC 20460
(202) 564-2855
muellerleile.caryn@epa.gov

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Friday, July 07, 2017 10:44 AM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>
Cc: Nurse, Leanne <Nurse.Leanne@epa.gov>; James H. Kim [Ex. 6 Personal Privacy (PP)]; [Ex. 6 Personal Privacy (PP)] Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: briefings on OW actions

Adding Margo to this chain because I accidentally omitted her from my original email. We'll get back to you as soon.

From: Muellerleile, Caryn [<mailto:Muellerleile.Caryn@epa.gov>]
Sent: Friday, July 7, 2017 10:09 AM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]>
Cc: Nurse, Leanne <Nurse.Leanne@epa.gov>; Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: briefings on OW actions

Hello,

Additional update. EPA plans to provide the briefing presentation and draft charge questions prior to the meeting as we did for the first round. We agree that it would be helpful for everyone to have these a few days ahead of time. Below is our proposed agenda:

- Perchlorate BBDR Model Peer Review Outcome
 - Reviewers response to charge
 - EPA's actions on peer review recommendations
- Overview of Revisions to the BBDR Model
- MCLG Approaches
- Next Steps

Alternate suggested dates for the meeting: July 18 from 2-3pm or July 19 from 3-4pm. Let me know if either of these work for you.

Caryn Muellerleile
Regulatory Management Division
Office of Policy
US Environmental Protection Agency
1200 Pennsylvania Ave NW (1803A)
Washington, DC 20460
(202) 564-2855
muellerleile.caryn@epa.gov

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Thursday, July 06, 2017 3:23 PM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>
Cc: Nurse, Leanne <Nurse.Leanne@epa.gov>; James H Kim@ [Ex. 6 Personal Privacy (PP)]
Subject: RE: briefings on OW actions

Caryn,

Thanks for setting up the meeting for Monday. I was getting ready to send out an invitation to interagency reviewers when I realized three things: First, I'm worried that we may be giving Agencies too little time to identify and invite the appropriate people (especially with tomorrow being Friday). Second, even if the right people are able to participate in the call, they won't have much time to review the briefing material. Third, I think there is still some confusion about exactly what material EPA plans to provide in advance of the call and even what the briefing will cover. Can you please let me know whether you plan to provide OMB and reviewers with the draft BBDR model report or the draft MCLG approach report? We think it would be of great value to allow people to review those reports prior to the call so that they can ask more informed questions. Along similar lines could you please confirm that EPA plans to discuss the comments it received to the BBDR model and the changes made to the model in addition to the MCLG report?

I think that reviewers need at least several days (if not a week) to review the report(s) so if you can get those to me today to circulate we can set up the briefing for late next week. What do you think? Happy to discuss by phone if you think that's easier.

Vlad

From: Muellerleile, Caryn [mailto:Muellerleile.Caryn@epa.gov]
Sent: Wednesday, July 5, 2017 1:47 PM
To: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad EOP/OMB
< [Ex. 6 Personal Privacy (PP)] >
Cc: Nurse, Leanne <Nurse.Leanne@epa.gov>
Subject: RE: briefings on OW actions

Hello,

I'm seeking to set up another meeting day/time with you all and others (DOD, NASA, etc) to discuss EPA's peer review materials for perchlorate. Do any of the following days/times work for you?

Mon. 7/10 from 10-11 or 2-3
Wed. 7/12 from 10-11

Also, would you like to forward EPA's invitation or would you prefer to send me the names of other federal invitees?

thank you,
Caryn

Caryn Muellerleile
Regulatory Management Division
Office of Policy
US Environmental Protection Agency
1200 Pennsylvania Ave NW (1803A)

Washington, DC 20460
(202) 564-2855
muellerleile.caryn@epa.gov

From: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Thursday, June 15, 2017 5:09 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>
Cc: Nurse, Leanne <Nurse.Leanne@epa.gov>
Subject: RE: briefings on OW actions

The following time works for us. Please send us both an invite with a call in number. Thank you!
6/29/17 (Thurs) 3-4

From: Dorjets, Vlad EOP/OMB
Sent: Thursday, June 15, 2017 4:11 PM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>
Cc: Nurse, Leanne <Nurse.Leanne@epa.gov>; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: Re: briefings on OW actions

Caryn,

I am out of the office until Tuesday so please work with Margo to set up the peer review briefing.

Thanks,

Vlad

Sent from my iPhone

On Jun 15, 2017, at 7:58 AM, Muellerleile, Caryn <Muellerleile.Caryn@epa.gov> wrote:

Hello Vlad,

I am coordinating another OW briefing on perchlorate peer review. OW has a tight timeline due to a deadline (explanation in blue text further below).

We have the following date & time suggestions for this briefing:

- 6/29/17 (Thurs) 11-12 or 3-4
- 6/30/17 (Fri) 9-10
- 7/3/17 (Mon) 10-11 or 11-12

Please let me know if you have questions or alternate suggestions. OW is working on materials to share with interagency partners for this briefing.

Thank you,
Caryn
202-564-2855

The perchlorate SDWA action has deadlines that are established under a consent decree. The first consent decree deadline is for completion of the expert peer review by October 18, 2017 of materials to inform EPA's SDWA action on perchlorate. While this is a unenforceable date, the EPA would need to file a letter with the court explaining why we did not meet the deadline. The consent decree also established enforceable deadlines of October 2018 for a proposal and December 2019 for final. Delay in completing the expert peer review will severely limit the timeframe for EPA to develop a proposal.

From: Dorjets, Vlad [Ex. 6 Personal Privacy (PP)]
Sent: Wednesday, June 15, 2016 11:03 AM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>
Subject: RE: briefings on OW actions

Thanks for setting this up. I need to coordinate with some other folks over here and will get back to you.

From: Muellerleile, Caryn [<mailto:Muellerleile.Caryn@epa.gov>]
Sent: Tuesday, June 14, 2016 5:01 PM
To: Dorjets, Vlad [Ex. 6 Personal Privacy (PP)]
Subject: RE: briefings on OW actions

Hello Vlad,

Regarding the Perchlorate peer review activities briefing with OW, a few date/time offerings:

Monday, June 20 @ 2:00 p.m.
Wed., June 22 @ 9:00 a.m.
Thurs, June 30 @ 2 p.m. or 3 p.m.

Caryn Muellerleile
Regulatory Management Division
Office of Policy
US Environmental Protection Agency
1200 Pennsylvania Ave NW (1803A)
Washington, DC 20460
(202) 564-2855
muellerleile.caryn@epa.gov

From: Dorjets, Vlad [Ex. 6 Personal Privacy (PP)]
Sent: Tuesday, June 07, 2016 3:09 PM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>
Subject: RE: briefings on OW actions

Thanks for checking. I actually don't remember what prompted my request for a briefing on stormwater but I'm sure there was a reason. I can definitely confirm the other two. Also, I sent a request to Nicole this morning for yet another briefing. I'll forward that email you right away.

From: Muellerleile, Caryn [<mailto:Muellerleile.Caryn@epa.gov>]

Sent: Tuesday, June 07, 2016 3:05 PM

To: Dorjets, Vlad < **Ex. 6 Personal Privacy (PP)** >

Subject: briefings on OW actions

Hello Vlad,

Just checking in, as I understand there have been various requests on informational briefings on OW topics and I don't want to lose track of them all.

- 1) The Forest Roads update is scheduled for next Tuesday, 6/14 at 3:15. I hope that one still works for you.
- 2) Stormwater (overall status update) was something you requested during Reg Agenda review. I will schedule that in the near future, unless your request has changed in any way.
- 3) Peer review in perchlorate (ground water/drinking water). This one just came in to me from Nicole, but I can't schedule yet as many OW staff are out an SES conference. For this one, I hope to discuss potential schedule options with you next week.

Is there anything else I'm missing? Also, we will soon be sending another list of requests of non-significance for various OW rules, but that is not quite ready yet. At that time there may be additional questions or potential briefings to schedule.

Thank you,
Caryn

Caryn Muellerleile
Regulatory Management Division
Office of Policy
US Environmental Protection Agency
1200 Pennsylvania Ave NW (1803A)
Washington, DC 20460
(202) 564-2855
muellerleile.caryn@epa.gov

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 8/3/2017 6:08:30 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]
Subject: RE: Meeting w/ OMB on Perchlorate

Eric,

We look forward to the discussion too and thanks for sending this material. I'll make sure everybody over here has it even if they are unable to review it before the meeting. All of you have been cleared through security so you should be able to get into the building with a valid ID. Just come on up to the 9th floor. The conference rooms can be tricky to find so I'll come to the elevator banks on the 9th floor a little before 4:00.

Vlad

-----Original Message-----

From: Burneson, Eric [mailto:Burneson.Eric@epa.gov]
Sent: Thursday, August 3, 2017 2:01 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>
Subject: RE: Meeting w/ OMB on Perchlorate

Vlad:

We are looking forward to our discussion later today regarding the peer review of the draft Perchlorate MCLG Methodologies Document. I will be bringing copies of the attached materials that we have prepared for next week's discussion with the other Federal Agencies. While I do not expect you or your colleagues will have reviewed these prior to our meeting I wanted to get them to you electronically to facilitate any input you may have on these. Our intent is to share the charge and the briefing materials with the other Federal Agencies once we have gotten feedback from you. Thank you for all the helpful input thus far. I look forward to our discussion later today.

Eric

-----Original Message-----

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Thursday, July 27, 2017 3:16 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Meeting w/ OMB on Perchlorate

Eric,

We're all set to meet over here next Thursday, August 3rd, at 4:00 to discuss perchlorate. The meeting will take place in our new offices on the 9th floor of NEOB (Conference Room 9258). Please enter the names of whomever you think may attend in the link below by COB Tuesday.

Ex. 6 Personal Privacy (PP)

I have attached our comments/questions to help inform your agenda and our discussion in general. Note that these comments are very similar to the ones we sent you after our initial phone call. We understand that you have already answered/addressed some of these questions but we thought it might be helpful to go over them one more time so that we can be clear of your response.

Please don't hesitate to let me know if you have any questions about the attached list.

Vlad

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 6/1/2020 2:54:11 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Johnson, Ann [Johnson.Ann@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]
Subject: RE: perchlorate

Eric,

I appreciate you forwarding this to me. Since you already have a relationship with Henry, I don't have any concerns with you answering questions he may have. If he had submitted a comment or request that would be different and I would want to come to me from the OP-equivalent at HHS. That being said, if you ever receive a question you don't want to answer, for whatever reason, please feel free to direct people directly to me.

Vlad

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Monday, June 1, 2020 10:50 AM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Johnson, Ann <Johnson.Ann@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Subject: perchlorate

Vlad:

I am forwarding an exchange I just had with FDA regarding perchlorate since I believe it originates from Inter Agency review of the final notice. I replied directly to Henry from FDA because I coordinate periodically with him on issues related to bottled water. If there are any other inquiries I will forward them to you as well. Let me know if you would prefer that I handle inquiries like this differently in the future.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Burneson, Eric
Sent: Monday, June 01, 2020 10:42 AM
To: Kim, Henry <Henry.Kim@fda.hhs.gov>
Cc: Robin, Lauren (Posnick) <Lauren.Robin@fda.hhs.gov>
Subject: RE: Draft final EPA determination not to regulate perchlorate

Henry

I am well and safe and I hope the same is true for you.

Thank you for your question about California and Massachusetts. These two states set drinking water standards for perchlorate before EPA made a decision to regulate perchlorate in 2011. These states established their standards in

accordance with their State laws, see

>https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/Perchloratehistory.html<, and

><https://www.mass.gov/lists/perchlorate-background-information-and-standards>< for more information.

Regarding a State's ability to promulgate drinking water standards, the Safe Drinking Water Act does not prohibit a state from promulgating regulations that are more stringent than the National Primary Drinking Water Regulations. I hope this is helpful.

Eric Burneson, P.E.

Director of Standards and Risk Management

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

202 564 5250

From: Kim, Henry <Henry.Kim@fda.hhs.gov>

Sent: Monday, June 01, 2020 9:46 AM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Robin, Lauren (Posnick) <Lauren.Robin@fda.hhs.gov>

Subject: Draft final EPA determination not to regulate perchlorate

Hello Eric,

Hope you are well and keeping safe!

I am currently reviewing the subject document that was provided to FDA for review and had a question that hopefully you can answer or refer to someone who can.

Currently, Massachusetts and California have established a standard for perchlorate (2 and 6 µg/L, respectively). Can I assume these standards would still be in effect for the two states even though EPA will not establish a NPDWR for perchlorate? More generally, even when EPA decides not to regulate a contaminant in public drinking water under the SDWA, individual states can still do so?

Any assistance you can provide is much appreciated.

Regards,

Henry

Henry Kim, Ph.D.

Division of Plant Products and Beverages

Office of Food Safety

Center for Food Safety and Applied Nutrition

U.S. Food and Drug Administration

henry.kim@fda.hhs.gov

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/19/2020 4:04:12 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: RE: Perchlorate Update?

Okay, thanks.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, May 19, 2020 12:04 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: Perchlorate Update?

Vlad
It will not be today. We are still undergoing review at the policy level. Tomorrow at the earliest, more likely Weds.
Eric

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Tuesday, May 19, 2020 9:26 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Perchlorate Update?

Do you think Perchlorate will come in today? Tomorrow?

Appointment

From: Martin, Italy M. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/29/2020 4:44:35 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Kymn, Christine J. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Kluever, April N. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Grossman, Andrea L. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Varcoe, Andrew R. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Troutman, Joel D. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Brooke, Francis J. Jr. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Malpass, Robert H. EOP/WHO [Ex. 6 Personal Privacy (PP)]; DL CEQ RegReview [Ex. 6 Personal Privacy (PP)]; Hickey, Jonathan P. EOP/OVP [Ex. 6 Personal Privacy (PP)]; Sidler, Matthew R. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Burneson, Eric [Burneson.Eric@epa.gov]; Parikh, Pooja [Parikh.Pooja@epa.gov]

Subject: E.O. 12866 Meeting 2040-AF28 - National Primary Drinking Water Regulations: Regulation of Perchlorate
Location: TELCONFERENCE

Start: 6/5/2020 6:00:00 PM
End: 6/5/2020 6:30:00 PM
Show Time As: Tentative

Recurrence: (none)

This meeting was requested by: **American Water Works Association**

Client Name: **Kevin Morley**

Email: kmorley@awwa.org Phone: [Ex. 6 Personal Privacy (PP)]

Call-in: [Ex. 6 Personal Privacy (PP)] Conference ID: [Ex. 6 Personal Privacy (PP)]

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/19/2020 5:26:13 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: RE: Perchlorate Update?

That's the perfect table for what I need, thanks.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, May 19, 2020 1:24 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: Perchlorate Update?

Vlad:

I think you want to look at Table VI-1 on page 30542 of the proposal.

><https://www.federalregister.gov/documents/2019/06/26/2019-12773/national-primary-drinking-water-regulations-perchlorate><

Note that the numbers vary slightly depending on whether you are referring to samples, entry points or water systems, because some water systems had more than one sample or point of entry with perchlorate contamination. The numbers you have below are based on entry points. We generally refer to the numbers based on water systems in which case there are 15 systems above 18 ppb and the other number are the same.

Eric

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Tuesday, May 19, 2020 12:47 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: Perchlorate Update?

Quick question: In the proposed rule, you demonstrated that occurrence at 18 µg/L, 56 µg/L, and 90 µg/L was 17, 2, and 1 facilities, respectively. Could you please let me know the correct total number of facilities of which those form a part? I want to make sure I cite the correct number. Thanks!

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, May 19, 2020 12:04 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: Perchlorate Update?

Vlad

It will not be today. We are still undergoing review at the policy level. Tomorrow at the earliest, more likely Weds.
Eric

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Tuesday, May 19, 2020 9:26 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Perchlorate Update?

Do you think Perchlorate will come in today? Tomorrow?

Message

From: Dorjets, Vlad EOP/OMB
Sent: 6/4/2020 9:04:38 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]
Subject: RE: EO12866: OMB Comments on Perchlorate Notice
Attachments: EO12866 EPA Perchlorate Rule (USDA).docx

Murphy's Law is alive and well. Just as I clicked send on the message below, I received the attached comments from USDA. Having heard from all the agencies I knew may be interested in perchlorate (DOD, HHS/FDA, NASA, SBA), I did not expect anybody else to submit comments. I would appreciate it if you could incorporate these comments and your responses to them into your passback.

From: Dorjets, Vlad EOP/OMB
Sent: Thursday, June 4, 2020 5:00 PM
To: 'Burneson, Eric' <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Vlad

Message

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: 6/4/2020 9:00:24 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]
Subject: EO12866: OMB Comments on Perchlorate Notice
Attachments: EO12866 EPA Perchlorate Rule (OMB 06-04-20).docx

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

Vlad

Appointment

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: 5/28/2020 9:37:18 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]

Subject: Accepted: Perchlorate
Location: Skype Meeting

Start: 6/1/2020 5:00:00 PM
End: 6/1/2020 6:00:00 PM
Show Time As: Busy

Recurrence: (none)

Message

From: Dorjets, Vlad EOP/OMB <[Redacted]> **Ex. 6 Personal Privacy (PP)**
Sent: 6/12/2020 3:13:31 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]
Subject: RE: EO12866: OMB Comments on Perchlorate Notice
Attachments: EO12866 EPA Perchlorate Rule (OMB 06-12-20).docx

Attached please find some additional comments on the perchlorate notice. I have put them on top of the preliminary set I sent you earlier but highlighted them all in yellow and included "[6/12]" in all of them so you can search on that to find them. Please note that I spoke with USDA and these comments reflect a refined version of their comments below. Let me know if would help to discuss any of this by phone.

From: Dorjets, Vlad EOP/OMB <[Redacted]> **Ex. 6 Personal Privacy (PP)**
Sent: Thursday, June 11, 2020 6:42 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: Re: EO12866: OMB Comments on Perchlorate Notice

I'm going to go ahead and send you the comments I just received from USDA. I'm in the process of running some internal traps to see where OMB stands on these issues but wanted to flag them for you in the meantime. Also, these comments may not be the totality of additional comments I have.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Sent from my iPhone

On Jun 11, 2020, at 6:23 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:

Vlad:

Thank you for transmitting the provisional comments yesterday. We do not require a discussion of the comments. We have drafted a passback/response document. Before I ask for senior level EPA review I wanted to check with you to see if any more comments are forthcoming. You noted that the Inter Agency deadline was COB today, but based on recent experience, I am assuming we should wait until tomorrow morning before assuming that there will be no more comments.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Wednesday, June 10, 2020 2:07 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Eric,

Thanks again for addressing comments so quickly. Please note that I have not heard from all reviewers yet (I gave them until COB Thursday to get back to me) so the attached comments should be seen as provisional. That being said, I have heard back from SBA so wanted to go ahead and pass along their comments to you. I have clearly identified the follow-up comments submitted by SBA in the attached documents. Most are worded as helpful suggestions but let me know if you have any concerns. Also, I have fixed a number of typos but you may want to give the document a careful scrub as part of a final review. I realize that, by sending this document, I have created some version control challenges but I felt it was important to pass along SBA's comments now.

Feel free to give me a call if you want to discuss.

Vlad

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, June 9, 2020 5:41 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad;

Attached please find EPA's edits and responses to the consolidated comments received from the Inter Agency Review. We have accepted the majority of recommended edits and have offered alternative language where appropriate.

As we discussed DOJ has requested signature of this action not later than June 18, 2020. We therefore need OMB clearance by June 17.

We can meet to discuss any questions you have regarding the attached document. Thank you for your coordination and your input on this important action.

Eric Burneson, P.E.
Director of Standards and Risk Management

Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Friday, June 05, 2020 10:07 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks and that works. Note that I have just gotten off the phone with DOJ regarding whether [Ex. 5 Deliberative Process (DP)]
[Ex. 5 Deliberative Process (DP)]
[Ex. 5 Deliberative Process (DP)] I am not ready to offer any recommendation on [Ex. 5 Deliberative Process (DP)]
Ex. 5 Deliberative Process (DP)
[Ex. 5 Deliberative Process (DP)] Of course, SBA just issued a public letter
in the context of [Ex. 5 Deliberative Process (DP)]
[Ex. 5 Deliberative Process (DP)]
We can discuss further later today or next week.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Friday, June 5, 2020 9:15 AM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad

We received this additional set of EOP comment and we will fold this in with the OMB, SBA and USDA comments. I assume your deadline for inter agency comments was yesterday and there should be no more comments forthcoming.

Regarding this afternoon, I am not certain if we need a conversation at this stage as we are still evaluating the comments, but I would like to put a placeholder on your calendar for 3:30 just in case it is needed. I will follow up later this morning to confirm and let you know what if any topics we want to discuss. Does that work?

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Friday, June 05, 2020 8:58 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks for combining the comments. Unfortunately, I need to throw another curve ball because I received some late comments from an EOP reviewer that I have to pass on. They are attached. You will find that many are technical/stylistic but there are also a couple legal questions. I would appreciate it if you could incorporate these comments and responses into your master passback as well.

Sorry again for the piecemeal submission of comments. Hopefully, it's not a huge inconvenience for you and, if anything, has saved more time than it has cost.

As for chatting, I may have a little time after the EO meeting but I have an EO meeting on another rule at 3:00. We can play by ear but I'm happy to pencil in a chat at 2:30? Would just be me and you (in which case one of us can just call the other) or a broader group requiring a conference line? If we don't have enough time, I'm completely free after 3:00 meeting so would be happy pick think up at, say, 3:30 or 4:00.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Friday, June 5, 2020 8:33 AM

To: Dorjets, Vlad EOP/OMB <[REDACTED]> **Ex. 6 Personal Privacy (PP)**

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad: We have combined the three comment documents into a single file and will prepare a passback with this combined file. Are you available after the 12866 meeting with AWWA this afternoon in case we have any questions about the comments?

From: Dorjets, Vlad EOP/OMB <[REDACTED]> **Ex. 6 Personal Privacy (PP)**

Sent: Thursday, June 04, 2020 6:05 PM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Really sorry but it looks like I jumped the gun more than I had realized; I just received comments from SBA which I wasn't expecting. I'm not sure I agree with all of SBA's comments so, perhaps, once you've reviewed these and other comments we can chat briefly about options. Hopefully these are the last of the comments.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:05 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: 'Parikh, Pooja' <Parikh.Pooja@epa.gov>; 'Christ, Lisa' <Christ.Lisa@epa.gov>; 'Johnson, Ann' <Johnson.Ann@epa.gov>; 'Wehling, Carrie' <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Murphy's Law is alive and well. Just as I clicked send on the message below, I received the attached comments from USDA. Having heard from all the agencies I knew may be interested in perchlorate (DOD, HHS/FDA, NASA, SBA), I did not expect anybody else to submit comments. I would appreciate it if you could incorporate these comments and your responses to them into your passback.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:00 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to

Ex. 5 Deliberative Process (DP)

Vlad

Message

From: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]
Sent: 7/27/2017 8:04:45 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Dorjets, Vlad EOP/OMB Ex. 6 Personal Privacy (PP)
Subject: RE: Meeting w/ OMB on Perchlorate

Vlad, would it help if I sent you all of the names of the attendees who accepted the teleconference we hosted last week?

-----Original Message-----

From: Burneson, Eric
Sent: Thursday, July 27, 2017 3:46 PM
To: Dorjets, Vlad EOP/OMB Ex. 6 Personal Privacy (PP)
Cc: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>
Subject: RE: Meeting w/ OMB on Perchlorate

Thanks for setting this up Vlad. We will get names into the system by Tuesday and prepare for a good discussion on Thursday.
Also please note that I have asked Caryn to work with you on scheduling the Federal Agencies meeting here during the week of August 7. Please note that I assumed it would be easier to host the meeting here at EPA where we have several large conference rooms but if you would prefer to hold it at the NEOB we are perfectly willing to come there.
Eric

-----Original Message-----

From: Dorjets, Vlad EOP/OMB Ex. 6 Personal Privacy (PP)
Sent: Thursday, July 27, 2017 3:16 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Meeting w/ OMB on Perchlorate

Eric,

We're all set to meet over here next Thursday, August 3rd, at 4:00 to discuss perchlorate. The meeting will take place in our new offices on the 9th floor of NEOB (Conference Room 9258). Please enter the names of whomever you think may attend in the link below by COB Tuesday.

Ex. 6 Personal Privacy (PP)

I have attached our comments/questions to help inform your agenda and our discussion in general. Note that these comments are very similar to the ones we sent you after our initial phone call. We understand that you have already answered/addressed some of these questions but we thought it might be helpful to go over them one more time so that we can be clear of your response.

Please don't hesitate to let me know if you have any questions about the attached list.

Vlad

Message

From: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 8/8/2017 11:28:08 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Automatic reply: Perchlorate charge

I will be out of the office August 6-10. I will respond to your email when I return. For urgent inquiries, please contact James_H_Kim@ [Ex. 6 Personal Privacy (PP)]

Appointment

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: 6/5/2020 4:13:08 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]

Subject: Accepted: EO12866: OMB Comments on Perchlorate Notice
Location: Skype Meeting

Start: 6/5/2020 7:30:00 PM
End: 6/5/2020 8:00:00 PM
Show Time As: Busy

Recurrence: (none)

Message

From: Christ, Lisa [Christ.Lisa@epa.gov]
Sent: 10/5/2017 6:55:17 PM
To: kevin.bromberg@sba.gov; Burneson, Eric [Burneson.Eric@epa.gov]; Hafez, Ahmed [Hafez.Ahmed@epa.gov]
CC: James_H_Kim (Ex. 6 Personal Privacy (PP)); Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]
Subject: RE: Perchlorate Charge Question - question about Lisa's email discussion below

Hello Kevin and Jim,
Here's my attempt to clarify a couple things and respond to your questions.

JK: Basically, the explanation is that the log distribution results in the larger unit changes at the higher fT4 levels? Does this highlight an insensitivity of the BBDR model?

The smaller delta in fT4 is because the distribution of fT4 is decreased by a consistent ratio as the mean value of fT4 is decreased by perchlorate. Thus changes at *lower* percentiles require a *smaller* unit change to result in the consistent ratio and changes at *higher* percentiles results in *greater* unit changes.

The BBDR model prediction used is the central tendency (i.e., 50th percentile). Because the BBDR model can be calibrated to any given percentile, but does not predict the distribution of fT4 levels, it was necessary to derive a fT4 distribution to identify a hypothyroxinemic threshold. EPA assumed a lognormal distribution with a Geometric Standard Deviation based on 2 to 3 studies depending on the gestational week.

KB: My reaction, as noted in my earlier email, is this result COULD also be attributed to an inaccuracy of the derived regression equations. If we make reference to ADDITIONAL uncertainties in 6.5.6 – we should call out some specifics, I would suggest, rather than imply by omission that it is solely the function of distribution approaches.

Most of the regression analysis equations are simply: Change in neuro outcome = slope X the change in fT4. The regression equations play no part in the size of the change in fT4 from the distribution.

The derivation of the distribution is critical to understanding how the BBDR model output was used to identify a hypothyroxinemic threshold, and we believe the uncertainties are better highlighted in question 13 that discusses the derived fT4 distribution and not question 11 which focuses on the regression analyses. So as to not confound the two separate steps of the process, our suggested edits to question #13 (highlighted below) incorporate language identifying

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

More detail as to why the Lazarus, Casey and van Wassenauer studies are not in the report:

Lazarus: This study was not included as it did not specifically look at hypothyroxinemic individuals compared to non-hypothyroxinemic individuals. Lazarus et al. (2012) had two groups of individuals with abnormal thyroid function, one of which was treated with levothyroxine and one of which was not. Both the treated and untreated groups included people with hypothyroxinemia (low ft4, normal TSH), subclinical hypothyroidism (high TSH, normal ft4) and clinical hypothyroidism (low ft4, high TSH). The treated and untreated groups were compared based on cognitive outcomes. Therefore, no conclusion can be drawn from this study specific to hypothyroxinemia.

Casey: This study was not located in our literature review as it was published after January 2017, when finalized our searches. This study also does not specifically evaluate the question of “is there a connection between hypothyroxinemia and adverse health outcome”. The aim of this study was to evaluate if *treatment* of abnormal thyroid function, starting around 18 weeks, resulted in different cognitive outcomes compared to non-treated groups. The null finding from this study does not imply there is no relationship between hypothyroxinemia and adverse cognitive outcomes. The authors concluded that the treatment approach used in this randomized control trial does not significantly impact cognitive outcomes for hypothyroxinemic individuals.

van Wassenauer: This study, like the Casey and the Lazarus studies, is an intervention or treatment study. This study evaluated the treatment of prematurely born children (less than 30 weeks gestation) and not pregnant women. The authors found no significant difference with respect to Bayley’s scores between the treated and non-treated prematurely born children at 24 months of age.

From: Bromberg, Kevin L. [mailto:kevin.bromberg@sba.gov]

Sent: Wednesday, October 04, 2017 5:20 PM

To: Christ, Lisa <Christ.Lisa@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Hafez, Ahmed <Hafez.Ahmed@epa.gov>

Cc: James_H_Kim [Ex. 6 Personal Privacy (PP)]; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>

Subject: RE: Perchlorate Charge Question - question about Lisa's email discussion below

Lisa, I am confused by your statement in the last paragraph that neither Casey nor CATS did investigate cognitive outcomes. Both CATs and Casey – both large studies – studied cognitive outcome for offspring of mothers with hypothyroxinemia – see two paragraphs below from the Casey 2017 study. Why did your note indicate otherwise? Why aren’t studies of treatment to normal hormone levels relevant to this evaluation of neurodevelopmental effects? Thanks for the Cooper and Pearce article, which does raise some issues. (All studies have issues!) I think these studies should be added to the report in some abbreviated form, at a minimum to the Group 1 reports (quantitative analysis of ft4).

<http://www.nejm.org/doi/full/10.1056/NEJMoa1606205#t=articleResults> Casey Study

The results of our trials are consistent with those of the CATS study, which was a thyroid-screening trial involving 21,846 pregnant women, primarily from the United Kingdom. Women in that trial were either screened immediately and treated with levothyroxine if they were identified as having subclinical hypothyroidism or hypothyroxinemia or had their serum frozen to be analyzed on completion of the pregnancy. The results of IQ testing of the children at 3 years of age did not differ significantly between children whose mothers had been immediately treated during the pregnancy and those whose mothers had treatment that was deferred.

Thyroid hormone-replacement therapy in the CATS study was initiated at a median gestational age of 13 weeks 3 days, as compared with 16 weeks 4 days and 18 weeks in our two trials.¹⁷ However, 24% of the children in the CATS study were lost to follow-up. In the current trials, the follow-up rate at 5 years of age was more than 92%.

Several studies have also suggested that either a high maternal thyrotropin level or hypothyroxinemia is associated with externalizing behavioral problems such as attention deficit-hyperactivity disorder (ADHD).^{25,26} In the Generation R Study, 8-year-old children of women from an iodine-deficient geographic area who had been identified with hypothyroxinemia before 20 weeks of gestation were found to have higher ADHD index scores than children of women without hypothyroxinemia.²⁶ This association persisted after adjustment for IQ. We did not identify any significant between-group differences in ADHD index scores in either of our trials, and the scores were well within the normal range. Moreover, the Child Behavior Checklist scores did not reveal any evidence of behavioral problems in children whose mothers with subclinical hypothyroidism or hypothyroxinemia were in the placebo group. The CATS study also did not detect any behavioral improvements in children who had been exposed to thyroid hormone replacement.¹⁷

From: Christ, Lisa [mailto:Christ.Lisa@epa.gov]
Sent: Wednesday, October 04, 2017 11:56 AM
To: Bromberg, Kevin L.; Burneson, Eric; Hafez, Ahmed
Cc: James H. Kim [mailto:James.H.Kim@epa.gov]; Hernandez-Quinones, Samuel
Subject: RE: Perchlorate Charge Question - My latest thoughts - feel free to modify

Kevin,

Thank you for the additional input on the charge. Also, I have summarized the discussion from yesterday.

You asked: Why do you see less affect (change in fT4 or change in IQ) at the 2.5th percentile than at the 50th percentile? Intuitively you would expect to see a greater affect when the mother has very low fT4, however, the affect is greater at the 50th percentile.

Response: Report tables 24, 30, 31, 32 and 33 provide results from studies by Finken, Pop and Vermiglio.

To develop these tables, EPA used the BBDR model output for the gestation week (12,13,16) that corresponds to the GW used in each study. Therefore, the BBDR predicted fT4 value at a zero dose of perchlorate differ.

The BBDR model output is the central tendency (i.e., 50th percentile). EPA created the distribution around the 50th percentile BBDR model output as described in Chapter 4 of the report.

There is uncertainty regarding the true fT4 levels at various percentiles in the distribution around the median output from the BBDR model. This is exemplified by the fact that in this analysis larger unit changes are being seen with increasing percentiles of fT4 in most analyses. The reason for this result is the log distribution assumed when developing the distribution around fT4, and the approach to developing distributions for each dose of perchlorate. Additional details on uncertainties can be found in section 6.5.6 of the report.

Also, we did receive and evaluate the studies you provided. Casey and the Lazarus (CATS) studies did not investigate the effects of hypothyroxinemia on cognitive outcome. They looked at kids born to women who were at 'low end of normal' thyroid function and who were either given or not given levothyroxine. There was no comparison to developmental outcome in children born to women with 'optimal' hormone levels. We also reviewed the Cooper and Pearce, 2017 paper which provided additional

perspectives. [http://www.sempr.org.br/files/1023/Beneficio do tratamento do hiposubclinico na gestacao Editor%20ial NEJM%202017.pdf](http://www.sempr.org.br/files/1023/Beneficio%20do%20tratamento%20do%20hiposubclinico%20na%20gestacao%20Editor%20ial%20NEJM%202017.pdf)

Best,

Lisa

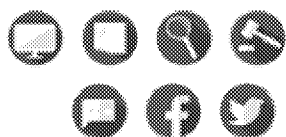
From: Bromberg, Kevin L. [mailto:kevin.bromberg@sba.gov]
Sent: Wednesday, October 04, 2017 11:33 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Hafez, Ahmed <Hafez.Ahmed@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Cc: James H Kim (Ex. 6 Personal Privacy (PP))
Subject: Perchlorate Charge Question - My latest thoughts - feel free to modify

Thanks for that thoughtful conversation yesterday.

Lisa and I just talked – and not I'm memorializing my latest thoughts.

Ex. 5 Deliberative Process (DP)

Kevin Bromberg
Assistant Chief Counsel for Environmental Policy
SBA // Office of Advocacy
409 3rd St. SW, Washington, D.C. 20416
kevin.bromberg@sba.gov 202.481.2963
202.205.6964



Message

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: 6/11/2020 10:35:13 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]
Subject: Re: EO12866: OMB Comments on Perchlorate Notice

Looks like I probably will have some additional comments. Will send them as soon as I can and suggest next steps.

Sent from my iPhone

On Jun 11, 2020, at 6:23 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:

Vlad:

Thank you for transmitting the provisional comments yesterday. We do not require a discussion of the comments. We have drafted a passback/response document. Before I ask for senior level EPA review I wanted to check with you to see if any more comments are forthcoming. You noted that the Inter Agency deadline was COB today, but based on recent experience, I am assuming we should wait until tomorrow morning before assuming that there will be no more comments.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: Wednesday, June 10, 2020 2:07 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Eric,

Thanks again for addressing comments so quickly. Please note that I have not heard from all reviewers yet (I gave them until COB Thursday to get back to me) so the attached comments should be seen as provisional. That being said, I have heard back from SBA so wanted to go ahead and pass along their comments to you. I have clearly identified the follow-up comments submitted by SBA in the attached documents. Most are worded as helpful suggestions but let me know if you have any concerns. Also, I have fixed a number of typos but you may want to give the document a careful scrub as part of a final review. I realize that, by sending this document, I have created some version control challenges but I felt it was important to pass along SBA's comments now.

Feel free to give me a call if you want to discuss.

Vlad

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, June 9, 2020 5:41 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad;

Attached please find EPA's edits and responses to the consolidated comments received from the Inter Agency Review. We have accepted the majority of recommended edits and have offered alternative language where appropriate.

As we discussed DOJ has requested signature of this action not later than June 18, 2020. We therefore need OMB clearance by June 17.

We can meet to discuss any questions you have regarding the attached document. Thank you for your coordination and your input on this important action.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: Friday, June 05, 2020 10:07 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks and that works. Note that I have just gotten off the phone with DOJ regarding whether this notice is **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)	I am not ready to offer any recommendation on Ex. 5 Deliberative Process (DP)
Ex. 5 Deliberative Process (DP)	
Ex. 5 Deliberative Process (DP)	Of course, SBA just issued a public letter in the context of the MSGP pushing back on that approach but I may be able to convince them to Ex. 5 Deliberative Process (DP)
Ex. 5 Deliberative Process (DP)	

We can discuss further later today or next week.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Friday, June 5, 2020 9:15 AM
To: Dorjets, Vlad EOP/OMB <[REDACTED]> **Ex. 6 Personal Privacy (PP)**
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad

We received this additional set of EOP comment and we will fold this in with the OMB, SBA and USDA comments. I assume your deadline for inter agency comments was yesterday and there should be no more comments forthcoming.

Regarding this afternoon, I am not certain if we need a conversation at this stage as we are still evaluating the comments, but I would like to put a placeholder on your calendar for 3:30 just in case it is needed. I will follow up later this morning to confirm and let you know what if any topics we want to discuss. Does that work?

From: Dorjets, Vlad EOP/OMB <[REDACTED]> **Ex. 6 Personal Privacy (PP)**
Sent: Friday, June 05, 2020 8:58 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks for combining the comments. Unfortunately, I need to throw another curve ball because I received some late comments from an EOP reviewer that I have to pass on. They are attached. You will find that many are technical/stylistic but there are also a couple legal questions. I would appreciate it if you could incorporate these comments and responses into your master passback as well.

Sorry again for the piecemeal submission of comments. Hopefully, it's not a huge inconvenience for you and, if anything, has saved more time than it has cost.

As for chatting, I may have a little time after the EO meeting but I have an EO meeting on another rule at 3:00. We can play by ear but I'm happy to pencil in a chat at 2:30? Would just be me and you (in which case one of us can just call the other) or a broader group requiring a conference line? If we don't have enough time, I'm completely free after 3:00 meeting so would be happy pick think up at, say, 3:30 or 4:00.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Friday, June 5, 2020 8:33 AM
To: Dorjets, Vlad EOP/OMB <[REDACTED]> **Ex. 6 Personal Privacy (PP)**
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad: We have combined the three comment documents into a single file and will prepare a passback with this combined file. Are you available after the 12866 meeting with AWWA this afternoon in case we have any questions about the comments?

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Thursday, June 04, 2020 6:05 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Really sorry but it looks like I jumped the gun more than I had realized; I just received comments from SBA which I wasn't expecting. I'm not sure I agree with all of SBA's comments so, perhaps, once you've reviewed these and other comments we can chat briefly about options. Hopefully these are the last of the comments.

From: Dorjets, Vlad EOP/OMB
Sent: Thursday, June 4, 2020 5:05 PM
To: 'Burneson, Eric' <Burneson.Eric@epa.gov>
Cc: 'Parikh, Pooja' <Parikh.Pooja@epa.gov>; 'Christ, Lisa' <Christ.Lisa@epa.gov>; 'Johnson, Ann' <Johnson.Ann@epa.gov>; 'Wehling, Carrie' <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Murphy's Law is alive and well. Just as I clicked send on the message below, I received the attached comments from USDA. Having heard from all the agencies I knew may be interested in perchlorate (DOD, HHS/FDA, NASA, SBA), I did not expect anybody else to submit comments. I would appreciate it if you could incorporate these comments and your responses to them into your passback.

From: Dorjets, Vlad EOP/OMB
Sent: Thursday, June 4, 2020 5:00 PM
To: 'Burneson, Eric' <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to

Ex. 5 Deliberative Process (DP)

Vlad

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 6/11/2020 10:25:21 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]
Subject: Re: EO12866: OMB Comments on Perchlorate Notice

I don't have any additional comments at this time but, to avoid what happened with initial draft (where I sent you multiple documents), I'd recommend waiting until tomorrow morning in case I get something later tonight.

Sent from my iPhone

On Jun 11, 2020, at 6:23 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:

Vlad:

Thank you for transmitting the provisional comments yesterday. We do not require a discussion of the comments. We have drafted a passback/response document. Before I ask for senior level EPA review I wanted to check with you to see if any more comments are forthcoming. You noted that the Inter Agency deadline was COB today, but based on recent experience, I am assuming we should wait until tomorrow morning before assuming that there will be no more comments.

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202 564 5250

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Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

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Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

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[Ex. 5 Deliberative Process (DP)]

I am not ready to offer any recommendation on [Ex. 5 Deliberative Process (DP)]

Ex. 5 Deliberative Process (DP)

[Ex. 5 Deliberative Process (DP)] Of course, SBA just issued a public letter in the context of the MSGP pushing back on that approach but I may be able to convince them to [Ex. 5 Deliberative Process (DP)]

[Ex. 5 Deliberative Process (DP)]

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Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

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Sent: Friday, June 05, 2020 8:58 AM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

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Sorry again for the piecemeal submission of comments. Hopefully, it's not a huge inconvenience for you and, if anything, has saved more time than it has cost.

As for chatting, I may have a little time after the EO meeting but I have an EO meeting on another rule at 3:00. We can play by ear but I'm happy to pencil in a chat at 2:30? Would just be me and you (in which case one of us can just call the other) or a broader group requiring a conference line? If we don't have enough time, I'm completely free after 3:00 meeting so would be happy pick think up at, say, 3:30 or 4:00.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Friday, June 5, 2020 8:33 AM

To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad: We have combined the three comment documents into a single file and will prepare a passback with this combined file. Are you available after the 12866 meeting with AWWA this afternoon in case we have any questions about the comments?

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: Thursday, June 04, 2020 6:05 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Really sorry but it looks like I jumped the gun more than I had realized; I just received comments from SBA which I wasn't expecting. I'm not sure I agree with all of SBA's comments so, perhaps, once you've reviewed these and other comments we can chat briefly about options. Hopefully these are the last of the comments.

From: Dorjets, Vlad EOP/OMB
Sent: Thursday, June 4, 2020 5:05 PM
To: 'Burneson, Eric' <Burneson.Eric@epa.gov>
Cc: 'Parikh, Pooja' <Parikh.Pooja@epa.gov>; 'Christ, Lisa' <Christ.Lisa@epa.gov>; 'Johnson, Ann' <Johnson.Ann@epa.gov>; 'Wehling, Carrie' <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Murphy's Law is alive and well. Just as I clicked send on the message below, I received the attached comments from USDA. Having heard from all the agencies I knew may be interested in perchlorate (DOD, HHS/FDA, NASA, SBA), I did not expect anybody else to submit comments. I would appreciate it if you could incorporate these comments and your responses to them into your passback.

From: Dorjets, Vlad EOP/OMB
Sent: Thursday, June 4, 2020 5:00 PM
To: 'Burneson, Eric' <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to

Ex. 5 Deliberative Process (DP)

Vlad

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 7/13/2017 8:15:46 PM
To: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]
CC: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; James_H_Kim@ [Ex. 6 Personal Privacy (PP)]
Subject: OMB Comments on Perchlorate Briefing
Attachments: EPA Perchlorate - OMB comments 7-6-17.docx

Caryn,

Attached please find OMB's comments on EPA's recent briefing on the Perchlorate peer review process and on efforts to regulate percholorate in general. To the extent that these comments can be address in Tuesday's interagency briefing, we woud find that helpful. Otherwise, we can discuss these items offline with you.

Don't hesitate to let us know if you have any questions.

Vlad

Message

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: 6/5/2020 12:58:25 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]
Subject: RE: EO12866: OMB Comments on Perchlorate Notice
Attachments: EO12866 EPA Perchlorate Rule (OMB 06-05-20).docx

Thanks for combining the comments. Unfortunately, I need to throw another curve ball because I received some late comments from an EOP reviewer that I have to pass on. They are attached. You will find that many are technical/stylistic but there are also a couple legal questions. I would appreciate it if you could incorporate these comments and responses into your master passback as well.

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From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Friday, June 5, 2020 8:33 AM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad: We have combined the three comment documents into a single file and will prepare a passback with this combined file. Are you available after the 12866 meeting with AWWA this afternoon in case we have any questions about the comments?

From: Dorjets, Vlad EOP/OMB [mailto:] **Ex. 6 Personal Privacy (PP)**
Sent: Thursday, June 04, 2020 6:05 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

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From: Dorjets, Vlad EOP/OMB
Sent: Thursday, June 4, 2020 5:05 PM
To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: 'Parikh, Pooja' <Parikh.Pooja@epa.gov>; 'Christ, Lisa' <Christ.Lisa@epa.gov>; 'Johnson, Ann' <Johnson.Ann@epa.gov>; 'Wehling, Carrie' <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Murphy's Law is alive and well. Just as I clicked send on the message below, I received the attached comments from USDA. Having heard from all the agencies I knew may be interested in perchlorate (DOD, HHS/FDA, NASA, SBA), I did not expect anybody else to submit comments. I would appreciate it if you could incorporate these comments and your responses to them into your passback.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:00 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>;

Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

Vlad

Appointment

From: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]
Sent: 6/19/2017 2:56:08 PM
To: Hafez, Ahmed [Hafez.Ahmed@epa.gov]; Strong, Jamie [Strong.Jamie@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Grevatt, Peter [Grevatt.Peter@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Olson, Daniel [Olson.Daniel@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Vlad Dorjets [Ex. 6 Personal Privacy (PP)]
CC: Behl, Betsy [Behl.Betsy@epa.gov]; OP ADP Calendar [OP_ADP_Calendar@epa.gov]; Nurse, Leanne [Nurse.Leanne@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]
Subject: Perchlorate Peer Review Briefing with EPA
Location: [Ex. 6 Personal Privacy (PP)] access code [Ex. 6 Personal Privacy (PP)]
Start: 6/29/2017 7:00:00 PM
End: 6/29/2017 8:00:00 PM
Show Time As: Tentative

Use conference line [Ex. 6 Personal Privacy (PP)] and access code [Ex. 6 Personal Privacy (PP)]

Appointment

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: 6/2/2020 6:13:54 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]

Subject: Call w/ DOJ re Perchlorate
Location: **Ex. 6 Personal Privacy (PP)**

Start: 6/4/2020 8:00:00 PM
End: 6/4/2020 9:00:00 PM
Show Time As: Tentative

Recurrence: (none)

Message

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: 6/2/2020 6:08:43 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]
Subject: RE: Perchlorate Question

Let's go with 4:00. I'll send an invitation.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, June 2, 2020 1:46 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Perchlorate Question

Vlad;
Would 2:00 or 4:00 work for you?
Eric

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: Tuesday, June 02, 2020 1:05 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Perchlorate Question

Thanks for the quick response. That's what I thought you were doing but there are a couple places where I think the point is a little muddles so I will try to offer some minor tweaks.

Also, I just heard from DOJ and they have comments they would like to convey by phone. They are available Thursday after 11:00 a.m. (they also provided availability for Friday and Monday and Tuesday of next week but I think you would agree that the sooner we have this call the better). I have calls at 1:30 and 3:30 that I'd prefer to be on but can miss if necessary so can be pretty flexible that day. Could you please let me know availability on your end and I'll set up the call?

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, June 2, 2020 12:58 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Perchlorate Question

Vlad;

Ex. 5 Deliberative Process (DP)

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>
Sent: Tuesday, June 02, 2020 12:22 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>
Subject: Perchlorate Question

Eric,

I am re-reading the perchlorate notice and was hoping you could clarify one more thing for me. Is EPA saying that [REDACTED] Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

[REDACTED] Ex. 5 Deliberative Process (DP) This point is a bit muddled so it would help me understand your intention before I try to suggest edits.

Thanks,

Vlad

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/15/2020 4:25:47 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Re: Assume you saw the NYT article?

Do you have an ETA on when I can expect the rule? As expected, I'm fielding lots of questions on this as result of yesterday's article.

Sent from my iPhone

On May 14, 2020, at 2:16 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:

See the link below from the release
><https://www.epa.gov/sdwa/fact-sheets-perchlorate-drinking-water><

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Thursday, May 14, 2020 1:07 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: Assume you saw the NYT article?

Thanks. What "information" are you releasing today?

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Thursday, May 14, 2020 1:06 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: Assume you saw the NYT article?

For your awareness, EPA issued the following press release today >><https://www.epa.gov/newsreleases/epa-notes-successes-reducing-perchlorate-drinking-water><<; (and pasted below).

Today, the U.S. Environmental Protection Agency (EPA) is releasing information on reductions of perchlorate in drinking water due to actions that its partners and the agency have taken to mitigate this contaminant and protect public health. The agency is also providing information for drinking water utilities on perchlorate.

"Because of steps that EPA, states and public water systems have taken to identify, monitor and mitigate perchlorate, the levels have decreased in drinking water" **said EPA Administrator Andrew Wheeler**. "This success demonstrates that EPA and states are working together to lead the world in providing safe drinking water to all Americans."

Since EPA made a determination to regulate perchlorate in drinking water in 2011, meaningful reductions have occurred due to actions taken by EPA, states and public water systems. The main factors contributing to the decrease in perchlorate levels include:

- Improved procedures for storage and handling of hypochlorite solutions used as drinking water disinfectants.
- Remediation activities at 60 Superfund sites to address perchlorate.
- Drinking water regulations for perchlorate in Massachusetts and California.
- Federal and state remediation activities at perchlorate contaminated sites, particularly the ongoing remediation efforts in the state of Nevada to address perchlorate contamination in groundwater adjacent to the lower Colorado River upstream of Lake Mead.

EPA remains committed to continuing to work with states and public water systems and is providing information to water systems on addressing perchlorate in drinking water. For more information on the declining levels of perchlorate in drinking water and information for drinking water utilities: <https://www.epa.gov/sdwa/fact-sheets-perchlorate-drinking-water>.

Background

On June 26, 2019, EPA published the notice of proposed rulemaking seeking public comment on a range of options regarding the regulation of perchlorate in public drinking water systems. EPA is developing a final action that reflects comments received on the agency's proposal and will be issued this June. For more information about EPA's proposal, see www.epa.gov/sdwa/perchlorate-drinking-water.

Perchlorate is commonly used in solid rocket propellants, munitions, fireworks, airbag initiators for vehicles, matches, and signal flares. Perchlorate may occur naturally, particularly in arid regions such as the southwestern U.S., and can be found as a byproduct in hypochlorite solutions used for treating drinking water and nitrate salts used to produce fertilizers, explosives, and other products.

From: Dorjets, Vlad EOP/OMB <Ex. 6 Personal Privacy (PP)>
Sent: Thursday, May 14, 2020 12:40 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Assume you saw the NYT article?

Appointment

From: Falk Curtin, Edna T. EOP/OMB [Ex. 6 Personal Privacy EOP (PP)]
Sent: 9/22/2017 3:50:44 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Declined: EPA Perchlorate Peer Review Charge follow up
Location: Teleconference # [Ex. 6 Personal Privacy (PP)] code [Ex. 6 Personal Privacy (PP)] or EPA WJC East Room 2123
Start: 10/2/2017 7:00:00 PM
End: 10/2/2017 8:00:00 PM
Show Time As: Busy

Recurrence: (none)

Appointment

From: Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy EOP (PP)]
Sent: 9/22/2017 3:18:45 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Accepted: EPA Perchlorate Peer Review Charge follow up
Location: Teleconference # [Ex. 6 Personal Privacy (PP)] code [Ex. 6 Personal Privacy (PP)] or EPA WJC East Room 2123
Start: 10/2/2017 7:00:00 PM
End: 10/2/2017 8:00:00 PM
Show Time As: Busy

Recurrence: (none)

Appointment

From: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy EOP (PP)]

Sent: 9/22/2017 1:32:06 PM

To: Burneson, Eric [Burneson.Eric@epa.gov]

Subject: Accepted: EPA Perchlorate Peer Review Charge follow up

Location: Teleconference # [Ex. 6 Personal Privacy (PP)] code [Ex. 6 Personal Privacy (PP)] or EPA WJC East Room 2123

Start: 10/2/2017 7:00:00 PM

End: 10/2/2017 8:00:00 PM

Show Time As: Busy

Recurrence: (none)

Appointment

From: Barringer, Jody M. EOP/OMB [Ex. 6 Personal Privacy EOP (PP)]
Sent: 9/22/2017 1:05:55 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Accepted: EPA Perchlorate Peer Review Charge follow up
Location: Teleconference # [Ex. 6 Personal Privacy (PP)] code [Ex. 6 Personal Privacy (PP)] or EPA WJC East Room 2123
Start: 10/2/2017 7:00:00 PM
End: 10/2/2017 8:00:00 PM
Show Time As: Busy

Recurrence: (none)

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 7/24/2017 10:07:06 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: RE: Perchlorate

I really appreciate it. Please go ahead and call me at [Ex. 6 Personal Privacy (PP)] It's possible I'll be free as early as 4:00. If that is the case I'll let you know so that I don't have to keep you any later than I have to. Either way, thanks.

-----Original Message-----

From: Burneson, Eric [mailto:Burneson.Eric@epa.gov]
Sent: Monday, July 24, 2017 6:04 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: Perchlorate

5:00 is fine Vlad.

-----Original Message-----

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Monday, July 24, 2017 6:02 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: Perchlorate

I should be able to do 4:30 if that's any better. Otherwise, I'm free all Wednesday afternoon if you prefer we speak.

-----Original Message-----

From: Burneson, Eric [mailto:Burneson.Eric@epa.gov]
Sent: Monday, July 24, 2017 6:01 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: Perchlorate

Alas no 5:00 is not too late. I will try to loop in Jennifer McLain (the Deputy Office Director here in OGWDW). Shall we call you?

-----Original Message-----

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Monday, July 24, 2017 5:38 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: Perchlorate

Nothing urgent but appreciate the offer. Is 5:00 (or around then) too late for us to speak?

-----Original Message-----

From: Burneson, Eric [mailto:Burneson.Eric@epa.gov]
Sent: Monday, July 24, 2017 5:35 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: Perchlorate

Yes Vlad I would suggest a conversation after 3:30 since I am meeting with folks tomorrow morning and early afternoon to see what options we have for moving forward and addressing concerns. However if you have a more urgent need to discuss I am also available at 10:30 or 1:00.

Eric Burneson, P.E.
Director of Standards and Risk Management Office of Ground Water and Drinking Water U.S. Environmental Protection Agency
202 564 5250

-----Original Message-----

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Monday, July 24, 2017 5:28 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Perchlorate

Eric - I'm back in the office and trying to get caught up on perchlorate. I've already spoken with Jim K. about last week's briefing but am a little confused about next steps. Do you (or somebody in your office) have a couple minutes to chat tomorrow?

Message

From: Bromberg, Kevin L. [kevin.bromberg@sba.gov]
Sent: 5/31/2019 2:36:25 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]
CC: Dorjets, Vlad [REDACTED] Ex. 6 Personal Privacy (PP) Khera, Rajiv [Khera.Rajiv@epa.gov]
Subject: RE: Perchlorate _HRRCA Revised at 4.2.1.2 _ Need to Correct Error

Eric, thanks very much for that reply. I am always impressed by your dedication and ability. (I'm not at your level.)

The EPA response below does explain that dietary dose was not included, and how it would affect the benefits analysis, and this is an improvement over the previous HRRCA text where the discussion of the dietary dose was previously omitted – leaving doubt about how the modeling of dietary dose was done. In the absence of text, the reader could have assumed that EPA used the high rate adopted in the MCLG derivation as I did.

The only remaining problem is a small one.

I agree with your statement below: “EPA used a high exposure estimate of dietary intake to derive an MCLG, which is consistent with the objective of deriving a protective MCLG. MCLG derivation is a fundamentally different exercise than modeling health risk benefits.”

But EPA did state in the HRRCA regarding the water intake assumption: “The EPA has chosen to apply the 90th percentile drinking water intake rate in order to remain consistent with the assumption made in supporting the derivation of the MCLG.” Now, I know that EPA did not follow this approach for the dietary dose. A complete explanation would explain why it was best practice to fix the drinking water exposure to the MCLG derivation, whereas EPA decided to not use the high dietary dose assumption that was used in the MCLG, but substitute zero dose instead. Did EPA provide in the HRRCA another reason why linking to the MCLG was the better approach, instead of just simply being “consistent”? EPA is not being “consistent” on dietary dose. I vaguely recall that EPA may have addressed an additional reason or reasons for this choice in the interagency comments back to OMB very late in the review. Should this reason or reasons be added back into the HRRCA, rather than simply reside in interagency discussions?

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Friday, May 31, 2019 10:12 AM
To: Bromberg, Kevin L. <kevin.bromberg@sba.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Cc: Dorjets, Vlad [REDACTED] Ex. 6 Personal Privacy (PP) Khera, Rajiv <Khera.Rajiv@epa.gov>
Subject: RE: Perchlorate _HRRCA Revised at 4.2.1.2 _ Need to Correct Error

Kevin:

EPA's perchlorate benefit modeling does not mistakenly exclude dietary perchlorate exposure. The proposed rule is unlikely to have a significant impact on perchlorate in food products, therefore the benefits estimate focuses upon change in exposure from reduced perchlorate in drinking water at two public water system entry points that currently have concentrations greater than the proposed MCL of 56 µg/L.

EPA used a high exposure estimate of dietary intake to derive an MCLG, which is consistent with the objective of deriving a protective MCLG. MCLG derivation is a fundamentally different exercise than modeling health risk benefits. For the benefits analysis, EPA used two dose-response functions to estimate the potential effects of perchlorate exposure among population served by entry points with baseline perchlorate concentrations greater than the proposed MCL. The first function predicted the level of fT4 associated with a particular iodine intake and perchlorate exposure.

The second function predicted a change in IQ for the child of exposed pregnant mother given a change in fT4 associated with a change in perchlorate exposure. EPA applied these dose-response functions to baseline and post-rule scenarios assuming that only the drinking water exposure to perchlorate changed. EPA excluded a dietary dose from the perchlorate exposure concentrations used in the benefits analysis because the Agency assumed exposure from diet would not change from the baseline to post-rule.

As the example below shows, this exclusion has minimal impact on the benefits estimates. The table below provides an example of the fT4 impact of a change in water concentration from 70 µg/L (baseline) to 45 µg/L (policy target equal to 80% of 56 µg/L). The fT4 regression parameters are for the lowest iodine intake range. Excluding a fixed dietary dose may understate the fT4 levels, but not the change. The second case in the table includes a constant hypothetical dietary intake equivalent to 70 µg/L. The change in fT4, in either case is 0.02 pmol/L. Because the IQ dose-response function is log-linear, the IQ effect is slightly more pronounced at the lower fT4 levels that include dietary exposure. As the example shows, the change in IQ is 0.7% higher. Therefore, excluding dietary exposure introduces a slight downward bias in the benefits analysis.

Perchlorate Concentration (drinking water equivalent µg/L)	$fT4 = \beta \times P + I$ (I = 8.26, β = -0.0008, P in µg/L)	$\Delta IQ = (\gamma \times \ln(fT4_1)) - (\gamma \times \ln(fT4_0))$ (γ = 17.26)
Benefits Analysis (HRRCA)		
70	8.204 (fT4 ₀)	0.0420
45	8.224 (fT4 ₁)	
Modified analysis including hypothetical supplemental dietary intake equivalent to 70 µg/L		
70+70=140	8.148 (fT4 ₀)	0.0423
70+45=115	8.168 (fT4 ₁)	
Percent increase in IQ impact of supplemental dietary intake		0.7%

Thanks for your interest in this important action. We look forward to working with you and other Federal partners as we move forward with a final action.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Bromberg, Kevin L. [mailto:kevin.bromberg@sba.gov]
Sent: Friday, May 31, 2019 9:34 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Cc: Dorjets, Vlad
Subject: RE: Perchlorate _HRRCA Revised at 4.2.1.2 _ Need to Correct Error

Hi Eric and Lisa – did you get a chance to review this note?

Thx
Kevin

From: Bromberg, Kevin L.
Sent: Friday, May 24, 2019 10:23 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>

Cc: Dorjets, Vlad <[Redacted] Ex. 6 Personal Privacy (PP)>

Subject: FW: Perchlorate _HRRCA Revised at 4.2.1.2 _ Need to Correct Error

Eric and Lisa – see below – please correct potential error in HRRCA before it is placed into the docket. I don't understand how this was handled, but I did try to get this resolved properly doing the process.

Congratulations on getting the proposal done.

Please advise as to outcome.

Thx
Kevin

From: Dorjets, Vlad EOP/OMB <[Redacted] Ex. 6 Personal Privacy (PP)>

Sent: Friday, May 24, 2019 10:02 AM

To: Bromberg, Kevin L. <kevin.bromberg@sba.gov>; Kluever, April N. EOP/OMB <[Redacted] Ex. 6 Personal Privacy (PP)>

Subject: RE: Perchlorate _HRRCA Revised at 4.2.1.2 _ Need to Correct Error

Kevin -- Feel free to reach out to EPA since OMB has concluded its review. If it turns out that [Redacted] Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

From: Bromberg, Kevin L. <kevin.bromberg@sba.gov>

Sent: Friday, May 24, 2019 9:57 AM

To: Dorjets, Vlad EOP/OMB <[Redacted] Ex. 6 Personal Privacy (PP)>; Kluever, April N. EOP/OMB

<[Redacted] Ex. 6 Personal Privacy (PP)>

Subject: FW: Perchlorate _HRRCA Revised at 4.2.1.2 _ Need to Correct Error

I'm going to share this note with Eric Burneson and Lisa Christ – unless you have a response this morning. It is not too late to modify the HRRCA – it can be fixed until Federal Register publication. Only the NPRM is public now.

Kevin

From: Bromberg, Kevin L.

Sent: Thursday, May 23, 2019 5:39 PM

To: Dorjets, Vlad EOP/OMB <[Redacted] Ex. 6 Personal Privacy (PP)>

Cc: Newcomb, Elisabeth J. <Elisabeth.Newcomb@sba.gov>; Schwab, Margo EOP/OMB <[Redacted] Ex. 6 Personal Privacy (PP)>

Subject: RE: Perchlorate _HRRCA Revised at 4.2.1.2 _ Need to Correct Error

"This corresponds to a perchlorate dose for food of 0.45 µg/kg/day. The EPA chose to use the 90th percentile bodyweight-adjusted perchlorate consumption from food using the 95th percentile TDS results to estimate the perchlorate RSC from drinking water."

We have a simple question for EPA. The above is the perchlorate dose for food chosen for the MCLG from the final preamble. What did EPA choose in the HRRCA – no dose at all? Why be consistent on the water perchlorate consumption and not the dietary perchlorate dose?

Kevin

From: Bromberg, Kevin L.

Sent: Thursday, May 23, 2019 11:47 AM

To: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>; [REDACTED] Ex. 6 Personal Privacy (PP)>
Cc: Newcomb, Elisabeth J. <Elisabeth.Newcomb@sba.gov>
Subject: RE: Perchlorate _HRRCA Revised at 4.2.1.2 _ Need to Correct Error

Ex. 5 Deliberative Process (DP)

This is what the HRRCA says about the water consumption assumption: “The EPA has chosen to apply the 90th percentile drinking water intake rate in order to remain consistent with the assumption made in supporting the derivation of the MCLG.” What happened to the dietary consumption? Consistent or eliminated?

The new HRRCA states:

“On the other hand, the EPA did not include a perchlorate dietary dose in the benefits analysis, which would be unchanged between baseline and proposed MCL scenarios if many areas do not irrigate with drinking water. For people who obtain a significant portion of their fruit, vegetables, and milk from areas irrigated with the water from the same sources as the drinking water, we would expect their exposure may drop with the reduction of perchlorate in local food products. Because of this and the natural log form of the IQ response function, this approach may slightly understate the avoided IQ decrement estimates.” Revised HRRCA at 4.2.1.2

Ex. 5 Deliberative Process (DP)

From NPRM preamble regarding the MCLG derivation:

“Table III-4 presents the mean and selected percentiles of the distribution of perchlorate dose from food for women ages 20-44, for both mean and 95th percentile perchlorate concentrations in food based on the TDS. To calculate the RSC, the EPA selected the 90th percentile dose of perchlorate from food, assuming a scenario where the food contained the 95th percentile perchlorate concentration. This corresponds to a perchlorate dose for food of 0.45 µg/kg/day. The EPA chose to use the 90th percentile bodyweight-adjusted perchlorate consumption from food using the 95th percentile TDS results to estimate the perchlorate RSC from drinking water.”

Ex. 5 Deliberative Process (DP)

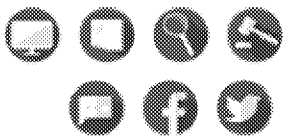
From: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP) [REDACTED]>
Sent: Thursday, May 23, 2019 11:06 AM
To: Bromberg, Kevin L. <kevin.bromberg@sba.gov>
Cc: Newcomb, Elisabeth J. <Elisabeth.Newcomb@sba.gov>
Subject: RE: Perchlorate

OMB has just concluded its review and EPA is planning on signing and rolling out this rule later today. There have been a couple more exchanges since the version you saw so there is no one document that captures all of the changes. I have attached final versions of the NPRM and HRRCA. Thanks for your help on this review! This one had some unique challenges but I think we got the package to a very good place.

From: Bromberg, Kevin L. <kevin.bromberg@sba.gov>
Sent: Thursday, May 23, 2019 9:47 AM
To: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP) [REDACTED]>; Kluever, April N. EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP) [REDACTED]>
Cc: Schwab, Margo EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP) [REDACTED]> Newcomb, Elisabeth J. <Elisabeth.Newcomb@sba.gov>
Subject: Perchlorate

Could we see the revised HRRCA and preamble (redlines)? Is the review complete?

📧 Kevin Bromberg
Assistant Chief Counsel for Environmental Policy
📍 SBA // Office of Advocacy
409 3rd St. SW, Washington, D.C. 20416
✉ kevin.bromberg@sba.gov 📞 202.481.2963
📠 202.205.6964



Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/8/2019 9:53:16 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Nickerson, William [Nickerson.William@epa.gov]
Subject: RE: Perchlorate Status Check

I understand that your leadership will want to review the documents before they are submitting but I'm wondering if it would make sense for us to talk to the extent that there are significant comments you do not anticipate being able to address. Similarly, do you have any questions or otherwise want to discuss any of OMB's comments? If there is anything we can do now to be more efficient when you submit the documents formally, I'm happy to do it in the interest of time.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Wednesday, May 8, 2019 5:46 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: Perchlorate Status Check

Vlad
Thanks for checking. We are working as fast as we can to get through the comments and suggested edits. At this point given our leadership's expectations to review prior to resubmitting I don't think we will have a passback to you before early next week.
Happy to discuss further if you would like.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Wednesday, May 08, 2019 4:28 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: Perchlorate Status Check

Eric – I just wanted to check in and see how you were coming along on revised perchlorate docs. Are you able to give me an estimate on when you think you'll be able to get the revised docs back to me?

Message

From: Adams, Darryl [Adams.Darryl@epa.gov]
Sent: 5/23/2019 2:47:30 PM
To: Manibusan, Mary [Manibusan.Mary@epa.gov]
CC: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Burneson, Eric [Burneson.Eric@epa.gov]; Evalenko, Sandy [Evalenko.Sandy@epa.gov]; Nurse, Leanne [Nurse.Leanne@epa.gov]
Subject: RE: Uploaded new versions of Perchlorate, 2040-AF28 into ROCIS

Will do.

From: Manibusan, Mary
Sent: Thursday, May 23, 2019 10:44 AM
To: Adams, Darryl <Adams.Darryl@epa.gov>
Cc: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]> Burneson, Eric <Burneson.Eric@epa.gov>; Evalenko, Sandy <Evalenko.Sandy@epa.gov>; Nurse, Leanne <Nurse.Leanne@epa.gov>
Subject: Re: Uploaded new versions of Perchlorate, 2040-AF28 into ROCIS

Vlad,
Please confirm when OMB has officially concluded.
Thanks,
Mary

Sent from my iPhone

On May 23, 2019, at 10:41 AM, Adams, Darryl <Adams.Darryl@epa.gov> wrote:

Vlad et al,
I've uploaded the new versions into ROCIS. Please let me if there are any issues. Thank you.

<image003.jpg>

Darryl Adams
Regulatory Management Division
Office of Policy, U.S. EPA
202 564-6569
Mail Code 1803A, Room 3512D WJC North

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 4/22/2019 8:36:54 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Nickerson, William [Nickerson.William@epa.gov]; Huff, Lisa [Huff.Lisa@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]
Subject: RE: Proposed Perchlorate NPDWR

Excellent, thanks.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Monday, April 22, 2019 4:35 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Vlad:

Attached please find an updated Perchlorate Occurrence and Monitoring Document. This document is referenced as an EPA 2018 publication in the draft FRN but it has not yet been published. We have updated this document from the 2018 draft and we will release it when we open the docket for the proposed regulation. We will have to update our references to reflect the fact that it is a 2019 document prior to that time.

Let me know if you have any additional questions or concerns.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Burneson, Eric
Sent: Monday, April 22, 2019 12:22 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Christ, Lisa <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Cc: Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Vlad:

Attached please find the Draft Maximum Contaminant Level Goal Technical Support Document that you asked about. Also find attached the slides we plan to present at the inter-agency teleconference call on Thursday. I plan to send you the Occurrence and Monitoring Document by the end of the day today.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency

From: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>

Sent: Monday, April 22, 2019 9:21 AM

To: Christ, Lisa <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>

Subject: RE: Proposed Perchlorate NPDWR

Also, do you expect to be able to send me the draft TSD today? I'd like to send that to reviewers as soon as possible. I'm also interested in seeing whether it includes certain discussion that is absent from the NPRM and HRRCA such as [Ex. 5 Deliberative Process (DP)]

[Ex. 5 Deliberative Process (DP)]

From: Dorjets, Vlad EOP/OMB

Sent: Monday, April 22, 2019 9:18 AM

To: 'Christ, Lisa' <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>

Subject: RE: Proposed Perchlorate NPDWR

Lisa – It looks like there was some miscommunication. Sorry if my message wasn't clear. I already have the draft HRRCA since, as you correctly pointed out, it was submitted together with the draft NPRM for review. The document I'm interested in seeing is the *Perchlorate Occurrence and Monitoring Report*. It is referenced numerous times in the document and is dated 2018 – not 2019 – which leads me to believe it has already been released and is not part of the rulemaking package yet I can't find it online.

From: Christ, Lisa <Christ.Lisa@epa.gov>

Sent: Sunday, April 21, 2019 11:51 AM

To: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>

Subject: RE: Proposed Perchlorate NPDWR

Vlad,

The HRRCA has not been publicly released as all of the support documents for the proposal are still draft. We sent the draft HRRCA at the same time the proposal was sent to OMB. I'm attaching it again here with the proposal.

Lisa

From: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>

Sent: Friday, April 19, 2019 1:37 PM

To: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>

Subject: RE: Proposed Perchlorate NPDWR

Sam – One more request. I'm seeing lots of references in HRRCA to EPA's *Perchlorate Occurrence and Monitoring Report* dated 2018 (so assume it's been released already) but it does not come up in a Google search and is not included among the other key Perchlorate documents on your website. Could you please sent that to me too?

From: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Sent: Friday, April 19, 2019 12:58 PM
To: Dorjets, Vlad EOP/OMB <Ex. 6 Personal Privacy (PP)>; Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Hi Vlad,

I just noticed that I inadvertently provided an earlier version of Volume I which Eric forwarded to you. Attached is a revised version of Volume 1 which incorporates minor editorial changes to the document. Sorry for the inconvenience.

Also, in response to your request I am attaching Volumes 2 and 3 of the Report.

Thanks

Sam

=====

Samuel Hernández Quiñones, P.E.
Environmental Engineer
Office of Water
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
202-564-1735

"USEPA Protecting Human Health and the Environment"

From: Dorjets, Vlad EOP/OMB <Ex. 6 Personal Privacy (PP)>
Sent: Friday, April 19, 2019 12:01 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Eric/Lisa – Could you please share Volumes II and III?

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Wednesday, April 17, 2019 4:23 PM
To: Dorjets, Vlad EOP/OMB <Ex. 6 Personal Privacy (PP)>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Vlad:

We can provide the requested support documents. The first document has been shared previously with many of the other Federal Agencies (see my email to Jim Kim on July 11, 2018) but we are happy to share this document again. It is

attached to this email. The second document is currently under revision to incorporate some of the modifications we made just prior to submitting the proposed NPDWR. We expect to be able to send this document early next week.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Tuesday, April 16, 2019 3:54 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Eric,

Kevin Bromberg has apparently already skimmed (if not actually read) the NPRM and is requesting two documents referenced in the preamble: the "proposed approaches to inform the derivation of a maximum contaminant level goal for perchlorate in drinking water" (reference 2018d) and the TSD (reference 2018e). Could you please let me know the status of these two documents? In case they're not currently available or will not be available soon it would help me to understand what they documents do and do not contain.

Vlad

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, April 16, 2019 1:10 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: Proposed Perchlorate NPDWR

Vlad

Thanks for touching base regarding the perchlorate proposed drinking water regulation. As we discussed I have blocked time on April 25 at 3:00 pm for a briefing to the other Federal Agency's on the perchlorate proposal. We will send an updated presentation to you early next week for distribution to the other Agency partners. I am assuming this will be a teleconference but let me know if you or other Federal partners would be interested in coming to EPA Offices for the meeting and I can book a larger room for the discussion.

As I mentioned I will be out of the office Thursday and Friday this week but if you have questions about the draft proposal you can contact Lisa Christ in my absence. Lisa's number is 202 564 8354.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

Message

From: Manibusan, Mary [Manibusan.Mary@epa.gov]
Sent: 5/23/2019 2:43:47 PM
To: Adams, Darryl [Adams.Darryl@epa.gov]
CC: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Burneson, Eric [Burneson.Eric@epa.gov]; Evalenko, Sandy [Evalenko.Sandy@epa.gov]; Nurse, Leanne [Nurse.Leanne@epa.gov]
Subject: Re: Uploaded new versions of Perchlorate, 2040-AF28 into ROCIS

Vlad,
Please confirm when OMB has officially concluded.
Thanks,
Mary

Sent from my iPhone

On May 23, 2019, at 10:41 AM, Adams, Darryl <Adams.Darryl@epa.gov> wrote:

Vlad et al,
I've uploaded the new versions into ROCIS. Please let me if there are any issues. Thank you.

<image003.jpg>

Darryl Adams
Regulatory Management Division
Office of Policy, U.S. EPA
202 564-6569
Mail Code 1803A, Room 3512D WJC North

Home Agenda/Regs Agency EO Review Manage Documents

RIN: 2040-AF28 (201904)
Stage of Rulemaking: Proposed Rule Stage
Title: National Primary Drinking Water Regulations: Regulation of Perchlorate

Agency/Sub Agency: 2040 EPA/CW
Submitted By: Leanne Nurse

OMB Ref ID: 2040-A571
Submitted Date: 04/16/2019

Manage Documents 2040-AF28

Primary Document Versions:

Document	Version	Date Uploaded	Uploaded By
EPA Clean Revised for OMB Clearance NPDWR FRN D5-23-19.docx	2.0	05/23/2019	Darryl Adams
EO12858_SOWA NPDWR 2040-AF28 FRN Perchlorate Rule 20190415.docx	1.0	04/16/2019	Leanne Nurse

No file selected.

UPLOAD NEW VERSION

Regulatory Impact Analysis Document Versions:

Document	Version	Date Uploaded	Uploaded By
EPA Revised Clean for EO12858 Clearance - HRRCA Perchlorate NPDWR 5-23-19.docx	2.0	05/23/2019	Darryl Adams
EO12858_SOWA NPDWR 2040-AF28 FRN Perchlorate HRRCA 20190301.docx	1.0	04/16/2019	Leanne Nurse

No file selected.

Message

From: Dorjets, Vlad EOP/OMB <[REDACTED]>
Sent: 4/22/2019 1:23:48 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: RE: Proposed Perchlorate NPDWR

Perfect thanks! Don't recall whether you were away on vacation or work Thursday or Friday but hope you enjoyed a few days away from office.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Monday, April 22, 2019 9:21 AM
To: Dorjets, Vlad EOP/OMB <[REDACTED]>; Christ, Lisa <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Cc: Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Vlad;
The Occurrence and Monitoring document is not yet released. We referenced a 2018 version that we had internally in preparing the preamble. Since the document will not be released until the proposal is released we will likely need to update the reference to this document. We will send you an electronic copy of that document today of that document today along with the TSD and the slide presentation for Thursday.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

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Sent: Monday, April 22, 2019 9:18 AM
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Also, in response to your request I am attaching Volumes 2 and 3 of the Report.

Thanks

Sam

=====

Samuel Hernández Quiñones, P.E.
Environmental Engineer
Office of Water
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
202-564-1735

"USEPA Protecting Human Health and the Environment"

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Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Hernandez-Quinones, Samuel

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Subject: RE: Proposed Perchlorate NPDWR

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Eric Burneson, P.E.
Director of Standards and Risk Management
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Sent: Tuesday, April 16, 2019 1:10 PM

To: Dorjets, Vlad EOP/OMB <Ex. 6 Personal Privacy (PP)>

Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>

Subject: Proposed Perchlorate NPDWR

Vlad

Thanks for touching base regarding the perchlorate proposed drinking water regulation. As we discussed I have blocked time on April 25 at 3:00 pm for a briefing to the other Federal Agency's on the perchlorate proposal. We will send an updated presentation to you early next week for distribution to the other Agency partners. I am assuming this will be a teleconference but let me know if you or other Federal partners would be interested in coming to EPA Offices for the meeting and I can book a larger room for the discussion.

As I mentioned I will be out of the office Thursday and Friday this week but if you have questions about the draft proposal you can contact Lisa Christ in my absence. Lisa's number is 202 564 8354.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 4/16/2019 5:28:15 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]
Subject: RE: Proposed Perchlorate NPDWR

Eric,

It was good to talk to you. I think we have a good game plan for the review. I have already sent the documents out to interagency reviewers and, as we discussed, I announced a briefing at 3:00 on the 25th "to clarify any questions reviewers may have about what EPA is proposing and why in order to inform comments to OMB." As we agreed, those comments are due to me by 10:00 am the following Monday, the 29th. Hopefully, I'll be able to send everything to you by the end of that day but I may end up needing the following day too. In terms of the briefing, we can use my conference line. The number is [Ex. 6 Personal Privacy (PP)] and passcode is [Ex. 6 Personal Privacy (PP)]. I'll send out an invitation once I have a better sense of who wants to participate (I asked for interest on my email to agencies). If you could get me the updated slides on Monday that would be great. I will be out of the office on Tuesday and Wednesday so it won't be easy for me to share the deck with participants.

Hope you enjoy your time away from the office and I'll reach out to Lisa if anything comes up in your absence.

Vlad

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, April 16, 2019 1:10 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: Proposed Perchlorate NPDWR

Vlad

Thanks for touching base regarding the perchlorate proposed drinking water regulation. As we discussed I have blocked time on April 25 at 3:00 pm for a briefing to the other Federal Agency's on the perchlorate proposal. We will send an updated presentation to you early next week for distribution to the other Agency partners. I am assuming this will be a teleconference but let me know if you or other Federal partners would be interested in coming to EPA Offices for the meeting and I can book a larger room for the discussion.

As I mentioned I will be out of the office Thursday and Friday this week but if you have questions about the draft proposal you can contact Lisa Christ in my absence. Lisa's number is 202 564 8354.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/22/2019 5:02:57 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Nickerson, William [Nickerson.William@epa.gov]
Subject: RE: EPA Response to Inter Agency Review comments on Revised Perchlorate NPRM Docs

Perfect, thanks. Will get back to you as soon as I can.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Wednesday, May 22, 2019 12:53 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: EPA Response to Inter Agency Review comments on Revised Perchlorate NPRM Docs

Vlad:

Thank you for coordination of the Inter-Agency review of the proposed National Primary Drinking Water Regulation for Perchlorate. Attached please find the EPA's revised FR Notice and HRRCA. As discussed yesterday we have accepted the majority of the suggested edits and proposed modifications to the remaining comments/edits. We believe that the attached draft incorporates the approaches to resolving issues that we discussed yesterday. This revised document also includes the language that we transmitted to you yesterday about the benefit/cost justification. Note that we have made slight modifications to the language that was sent last night and marked the sentences changed. We believe that we have addressed the comments from the other Federal Agency's through the revisions in the attached documents as appropriate. At your request we have prepared a response to the NASA comments which is also attached. As we also discussed, the EPA would like to have signature on the proposed rule tomorrow, May 23. We recognize this is an extremely compressed schedule but we appreciate any action you can take to expedite clearance.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Monday, May 20, 2019 7:03 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: OMB Comments on Revised Perchlorate MCL Docs

Eric,

Attached please find OMB's comments on the revised NPRM and HRRCA associated with the proposed perchlorate MCL. You will find the comments on the HRRCA rather light (and include some technical/formatting fixes) but it may be necessary to update aspects of the document to reflect changes to the NPRM where most of our comments are located. As before, we have tried wherever possible to provide specific line edits to facilitate your review. That being said, we

weren't able to do that in all cases. In addition, there are the comments you should have received separately that were submitted by FDA, NASA, SBA, and DOD.

I would appreciate it if you could draft some sort of a response I can forward to NASA. I certainly don't think you'll have time to address each one of their comments but I think it would be a good idea for me to share something that demonstrates that EPA reviewed and considered their comments.

In the case of DOD, the document turned out to only have one comment which I have incorporated into my own comments so you can disregard that document. Separately, however, DOD expressed that they remain concerned about

Ex. 5 Deliberative Process (DP)

They have also pointed out that

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

I should add that I particularly interested in your responses to SBA's comments. Especially, their proposed text relating to Ex. 5 Deliberative Process (DP). I understand that you may not be able to insert SBA's text as drafted but I would like to get a better understanding of the concern to see if we can draft something that meets Kevin's needs. I also interested in your response to SBA's comments on Ex. 5 Deliberative Process (DP). Since the comments were included in a single comment bubble and were thus difficult to read, I have copied them below.

Ex. 5 Deliberative Process (DP)

Please let me know if you have any questions about the comments and I will prioritize making time to either reply or get on the phone. Otherwise, I understand that you are going to try to be prepared to discuss the comments at 3:30 and let me know if there are any show stoppers or issues that require elevation. Separately, I realize you are working on some language to address the concern communicated by phone this afternoon. Feel free to either incorporate it into the document or just sent me the language in question by email if it's ready before the rest of the document. We can then incorporate it separately once it's been agreed upon.

Vlad

Message

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: 5/20/2019 9:08:36 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Nickerson, William [Nickerson.William@epa.gov]
Subject: RE: SBA Comments on Perchlorate

Kevin has indicated that his comments are in bold on pages 45, 48, 64, 66, 77, 129, 130, 138, 139 and 145.

From: Dorjets, Vlad EOP/OMB
Sent: Monday, May 20, 2019 3:49 PM
To: 'Burneson, Eric' <Burneson.Eric@epa.gov>
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: SBA Comments on Perchlorate

Here are comments provided by SBA. I already let Kevin know that by providing his comments on the redline instead of the clean version, he has made it challenging to identify his comments and therefore I could not guarantee that we would see them all.

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/23/2019 8:28:13 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: RE: Proposed Perchlorate Drinking Water Regulation

Fantastic. Hope you have a great long weekend not thinking about perchlorate.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Thursday, May 23, 2019 4:27 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: Proposed Perchlorate Drinking Water Regulation

Yes the rule has been signed.

From: Dorjets, Vlad EOP/OMB [mailto: [Ex. 6 Personal Privacy (PP)]]
Sent: Thursday, May 23, 2019 4:26 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: Proposed Perchlorate Drinking Water Regulation

Thanks for sharing...and for incorporating our comments. Does this mean Wheeler signed the rule?

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Thursday, May 23, 2019 4:13 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Manibusan, Mary <Manibusan.Mary@epa.gov>
Subject: Proposed Perchlorate Drinking Water Regulation

Vlad: The following is the notice that we just sent out (incorporating your suggested edits). Thanks again for your assistance

Today, the U.S. Environmental Protection Agency (EPA) is releasing a notice of proposed rulemaking that seeks public input on a range of options regarding the regulation of perchlorate in public drinking water systems.

The agency is seeking comment on a proposed National Primary Drinking Water Regulation (NPDWR) for perchlorate to establish a Maximum Contaminant Level (MCL) and a health-based Maximum Contaminant Level Goal (MCLG) at 56 micrograms per liter.

In addition, the agency is seeking comment on three alternative regulatory options:

- An MCL and MCLG for perchlorate set at 18 micrograms per liter.
- An MCL and MCLG for perchlorate set at 90 micrograms per liter.
- Withdrawal of the agency's 2011 determination to regulate perchlorate in drinking water.

The agency is requesting comment on all relevant aspects of the proposed rule but is especially interested in the perchlorate monitoring and reporting requirements for public water systems and a list of treatment technologies that would enable water systems to comply with the MCL, including affordable compliance technologies for

small systems serving 10,000 persons or less. EPA is also requesting comment on its methodology for deriving the MCLG, the underlying assumptions and analysis of its cost and benefit estimates, and other specific items listed in the proposed rule.

Perchlorate is commonly used in solid rocket propellants, munitions, fireworks, airbag initiators for vehicles, matches, and signal flares. Perchlorate may occur naturally, particularly in arid regions such as the southwestern United States and is found as an impurity in hypochlorite solutions used for drinking water treatment and nitrate salts used to produce nitrate fertilizers, explosives, and other products.

EPA will accept public comment on the proposal for 60 days after publication in the Federal Register via <http://www.regulations.gov> [Docket ID No. EPA-HQ-OW-2018-0780].

For more information and to view the pre-publication version of the Federal Register Notice, visit <https://www.epa.gov/dwstandardsregulations/perchlorate-drinking-water>;

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

Message

From: Christ, Lisa [Christ.Lisa@epa.gov]
Sent: 4/21/2019 3:50:41 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]
CC: Nickerson, William [Nickerson.William@epa.gov]; Huff, Lisa [Huff.Lisa@epa.gov]
Subject: RE: Proposed Perchlorate NPDWR
Attachments: EO12866_SDWA NPDWR 2040-AF28 FRN Perchlorate HRRCA 20190412.docx

Vlad,
The HRRCA has not been publicly released as all of the support documents for the proposal are still draft. We sent the draft HRRCA at the same time the proposal was sent to OMB. I'm attaching it again here with the proposal.
Lisa

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Friday, April 19, 2019 1:37 PM
To: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Sam – One more request. I'm seeing lots of references in HRRCA to EPA's *Perchlorate Occurrence and Monitoring Report* dated 2018 (so assume it's been released already) but it does not come up in a Google search and is not included among the other key Perchlorate documents on your website. Could you please sent that to me too?

From: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Sent: Friday, April 19, 2019 12:58 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Hi Vlad,

I just noticed that I inadvertently provided an earlier version of Volume I which Eric forwarded to you. Attached is a revised version of Volume 1 which incorporates minor editorial changes to the document. Sorry for the inconvenience.

Also, in response to your request I am attaching Volumes 2 and 3 of the Report.

Thanks
Sam

=====

Samuel Hernández Quiñones, P.E.
Environmental Engineer
Office of Water
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
202-564-1735

"USEPA Protecting Human Health and the Environment"

From: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>
Sent: Friday, April 19, 2019 12:01 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Eric/Lisa – Could you please share Volumes II and III?

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Wednesday, April 17, 2019 4:23 PM
To: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Vlad:

We can provide the requested support documents. The first document has been shared previously with many of the other Federal Agencies (see my email to Jim Kim on July 11, 2018) but we are happy to share this document again. It is attached to this email. The second document is currently under revision to incorporate some of the modifications we made just prior to submitting the proposed NPDWR. We expect to be able to send this document early next week.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>
Sent: Tuesday, April 16, 2019 3:54 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Eric,

Kevin Bromberg has apparently already skimmed (if not actually read) the NPRM and is requesting two documents referenced in the preamble: the “proposed approaches to inform the derivation of a maximum contaminant level goal for perchlorate in drinking water” (reference 2018d) and the TSD (reference 2018e). Could you please let me know the status of these two documents? In case they’re not currently available or will not be available soon it would help me to understand what they documents do and do not contain.

Vlad

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Tuesday, April 16, 2019 1:10 PM

To: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP) >

Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>

Subject: Proposed Perchlorate NPDWR

Vlad

Thanks for touching base regarding the perchlorate proposed drinking water regulation. As we discussed I have blocked time on April 25 at 3:00 pm for a briefing to the other Federal Agency's on the perchlorate proposal. We will send an updated presentation to you early next week for distribution to the other Agency partners. I am assuming this will be a teleconference but let me know if you or other Federal partners would be interested in coming to EPA Offices for the meeting and I can book a larger room for the discussion.

As I mentioned I will be out of the office Thursday and Friday this week but if you have questions about the draft proposal you can contact Lisa Christ in my absence. Lisa's number is 202 564 8354.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/16/2019 3:10:41 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Nickerson, William [Nickerson.William@epa.gov]
Subject: RE: EPA Response to OMB Comments on Draft Perchlorate MCL NPRM (1 of 2)

Let's hold 3:00-4:00 on Wednesday in case a call is needed. Also, I appreciate the offer to speak before then. I'm going to start reading now and hope to be done by end of day. Most likely, if I have questions it won't be until tomorrow but I'll let you know.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Thursday, May 16, 2019 10:53 AM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: EPA Response to OMB Comments on Draft Perchlorate MCL NPRM (1 of 2)

Vlad:
Good thinking regarding a meeting on 5/22. We could be available in the afternoon at either 1:00, 3:00 or 4:00. Let us know which of these times work best and we will send a meeting request.

Also I want to repeat the request to make ourselves available for a conversation today or tomorrow to answer any clarifying questions you may have about our passback.

Eric

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Thursday, May 16, 2019 9:33 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: EPA Response to OMB Comments on Draft Perchlorate MCL NPRM (1 of 2)

Thanks for sending this. I'll start reviewing right away. As far as next steps go, I'm going to give agencies until 2:00 on Monday to send me comments and tell them that they should be prepared to elevate substantive concerns to policy officials. I'm planning on sending you updated comments by COB Monday (and hopefully early enough that you can start reviewing them that night). You'll probably need Tuesday to review and prepare responses so think we should plan to talk on Wednesday. In fact, it may be a good idea for us to throw some time on a calendar to ensure that both Margo and April are available too if needed. Can you let me know what times would work for you on Wednesday?

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Wednesday, May 15, 2019 6:40 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: EPA Response to OMB Comments on Draft Perchlorate MCL NPRM (1 of 2)

Vlad:

Thank you for facilitating Inter-Agency review and for providing many helpful comments and suggestions to improve the clarity of the proposed perchlorate drinking water regulation. Attached please find our responses to the comments and suggested edits you provided on the draft Federal Register Notice and Health Risk Reduction Cost Analysis (a.k.a. Economic Analysis). We agree with many of the suggested edits you provided and have denoted with a comment and strikeout where we disagree with the suggested edit and/or suggest alternative language. We have also provided a clean version of the revised FRN document if that is helpful.

While the details are in the attached documents, the following is a summary of key issues where we accepted some but not all of the changes suggested or have proposed alternative language:

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-
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Ex. 5 Deliberative Process (DP)

We believe the attached responses will provide greater clarity and rationale for the Agency's proposed regulation and the alternatives for comment. We must highlight that concluding that the health effects modeling represents the best available peer reviewed science is critical to proceeding either with a regulation or to a final withdrawal of the regulatory determination. We are available to discuss the attached responses and appreciate your continued attention to this important matter.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: Tuesday, April 30, 2019 8:16 PM
To: Nickerson, William <Nickerson.William@epa.gov>
Cc: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: OMB Comments on Draft Perchlorate MCL NPRM (1 of 2)

Bill,

Please find attached OMB's comments on EPA's draft proposal setting an MCL for perchlorate. Specifically, I have attached comments on the NPRM document and the HRRCA. I have also provide a separate set of comments on EPA's

Ex. 5 Deliberative Process (DP)

Please note that I am still awaiting comments from one particular agency. I explained the situation to Eric earlier today so he can provide additional context. I'm hoping to get clarity on the situation tomorrow.

Please don't hesitate to let me know if you have any questions about OMB's comments. In fact, once you have had a chance to review them, it may make sense for us to set up a call to get your reactions and answer any questions you may have. Either way, once I receive a revised set of documents from you, I intend to circulate them for a *very quick* interagency review. While I would normally prefer to get another round of staff-level comments before determining which outstanding concerns require elevation, I don't think we will have the luxury of doing that. When I circulate the comments for another round of review, I thus intend to specify agencies only provide substantive comments which have policy-level support.

Vlad

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/3/2019 8:10:30 PM
To: Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]
CC: Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]
Subject: RE: Interagency Comments on Draft Perchlorate NPDWR
Attachments: 190419_DRAFT MCLG TSD V1 -- FDA Comments 04-29-2019.docx

FDA comments only on TSD that go beyond page 6-5. Will let you know if there are additional CDC comments.

From: Dorjets, Vlad EOP/OMB
Sent: Friday, May 3, 2019 3:35 PM
To: 'Hernandez-Quinones, Samuel' <Hernandez.Samuel@epa.gov>
Cc: Burneson, Eric <Burneson.Eric@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: Interagency Comments on Draft Perchlorate NPDWR

Sam,

Thanks for flagging. It looks like the document is normal up until page 6-5 (page 36 of the document) and then gets screwy. I just spoke with HHS and they told us that they will confirm whether they had comments on text beyond page 6-5 but, unless we are told otherwise, we can assume all of their comments precede that page. I'll let you know if I hear anything different from them.

Vlad

From: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Sent: Thursday, May 2, 2019 1:51 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Burneson, Eric <Burneson.Eric@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: Interagency Comments on Draft Perchlorate NPDWR

Hi Vlad,

As we are reviewing the Interagency comments we noticed that one of the documents submitted by CDC appears to be incomplete/corrupted. (The document should have around 90 pages, but the CDC document shows 700 pages.)

The document is titled (EPA Perchlorate MCL TSD (CDC).docx) and it cuts off at chapter 6, so we are unable to see any comments submitted on chapters 7, 8, 9, 10, 11, 12, & 13.

Can you please resend the CDC file to us?

Thank You
Sam

=====

Samuel Hernández Quiñones, P.E.
Environmental Engineer
Office of Water

Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
202-564-1735

"USEPA Protecting Human Health and the Environment"

Message

From: Dorjets, Vlad EOP/OMB; **Ex. 6 Personal Privacy (PP)**
Sent: 5/22/2019 4:00:29 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Re: Perchlorate Status?

Fingers crossed

Sent from my iPhone

On May 22, 2019, at 11:53 AM, Dorjets, Vlad EOP/OMB <**Ex. 6 Personal Privacy (PP)**> wrote:

Any update on perchlorate passback?

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 4/19/2019 5:00:24 PM
To: Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]
CC: Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Huff, Lisa [Huff.Lisa@epa.gov]
Subject: RE: Proposed Perchlorate NPDWR

Thanks!

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Sent: Friday, April 19, 2019 12:58 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Hi Vlad,

I just noticed that I inadvertently provided an earlier version of Volume I which Eric forwarded to you. Attached is a revised version of Volume 1 which incorporates minor editorial changes to the document. Sorry for the inconvenience.

Also, in response to your request I am attaching Volumes 2 and 3 of the Report.

Thanks
Sam

=====

Samuel Hernández Quiñones, P.E.
Environmental Engineer
Office of Water
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
202-564-1735

"USEPA Protecting Human Health and the Environment"

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Friday, April 19, 2019 12:01 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Eric/Lisa – Could you please share Volumes II and III?

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Wednesday, April 17, 2019 4:23 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Hernandez-Quinones, Samuel

<Hernandez.Samuel@epa.gov>

Subject: RE: Proposed Perchlorate NPDWR

Vlad:

We can provide the requested support documents. The first document has been shared previously with many of the other Federal Agencies (see my email to Jim Kim on July 11, 2018) but we are happy to share this document again. It is attached to this email. The second document is currently under revision to incorporate some of the modifications we made just prior to submitting the proposed NPDWR. We expect to be able to send this document early next week.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB <Ex. 6 Personal Privacy (PP)>
Sent: Tuesday, April 16, 2019 3:54 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Eric,

Kevin Bromberg has apparently already skimmed (if not actually read) the NPRM and is requesting two documents referenced in the preamble: the "proposed approaches to inform the derivation of a maximum contaminant level goal for perchlorate in drinking water" (reference 2018d) and the TSD (reference 2018e). Could you please let me know the status of these two documents? In case they're not currently available or will not be available soon it would help me to understand what they documents do and do not contain.

Vlad

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, April 16, 2019 1:10 PM
To: Dorjets, Vlad EOP/OMB <Ex. 6 Personal Privacy (PP)>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: Proposed Perchlorate NPDWR

Vlad

Thanks for touching base regarding the perchlorate proposed drinking water regulation. As we discussed I have blocked time on April 25 at 3:00 pm for a briefing to the other Federal Agency's on the perchlorate proposal. We will send an updated presentation to you early next week for distribution to the other Agency partners. I am assuming this will be a teleconference but let me know if you or other Federal partners would be interested in coming to EPA Offices for the meeting and I can book a larger room for the discussion.

As I mentioned I will be out of the office Thursday and Friday this week but if you have questions about the draft proposal you can contact Lisa Christ in my absence. Lisa's number is 202 564 8354.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/23/2019 1:42:55 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Manibusan, Mary [Manibusan.Mary@epa.gov]
Subject: perchlorate
Attachments: EPA Responses to EO12886 Comments - HRRCA Perchlorate NPDWR 5-22-19 (05-23).docx; EPA Response to OMB edits Perchlorate NPDWR FRN 05-22-19 (OMB 05-22-19) (05-23).docx

Final edits.

Appointment

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 3/5/2019 10:48:45 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Accepted: Perchlorate Proposed NPDWR
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)] Conf ID [Ex. 6 Personal Privacy (PP)]
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Busy

Recurrence: (none)

Message

From: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>
Sent: 3/5/2019 10:48:29 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Re: Perchlorate

We're set for 4. Going to invite the new budget examiner for OGWDW, Jake Glass, too.

Sent from my iPhone

On Mar 5, 2019, at 5:13 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:

Will Do.

From: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>
Sent: Tuesday, March 05, 2019 5:10 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: Perchlorate

Eric – Thanks for getting back to me. Can we pencil in Thursday at 4:00? That time works for me but I need to check with Margo on her availability.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, March 5, 2019 4:24 PM
To: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>; Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: Perchlorate

Vlad: What is your availability on Thursday (3/7) afternoon at 2:00 pm or 4:00 pm?
Eric

From: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>
Sent: Monday, March 04, 2019 5:07 PM
To: Nickerson, William <Nickerson.William@epa.gov>
Cc: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Perchlorate

Bill,

Before you submit perchlorate for OMB review (which, hopefully, will be very soon), I would like to request a staff-level briefing so that we can get an understanding of what is in the rule. Specifically, we are interested in getting an overview of [REDACTED] Ex. 5 Deliberative Process (DP) [REDACTED] Ex. 5 Deliberative Process (DP). Please note that Rosario should be making a similar request to Brittany later today. I'm hoping we can do this in a brief call sometime later this week.

Thanks,

Vlad

Message

From: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/23/2019 12:05:47 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: Nickerson, William [Nickerson.William@epa.gov]; Kluever, April N. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: Latest Comments on Perchlorate

Looking at it now.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Wednesday, May 22, 2019 9:41 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Nickerson, William <Nickerson.William@epa.gov>; Kluever, April N. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)] Manibusan, Mary <Manibusan.Mary@epa.gov>
Subject: RE: Latest Comments on Perchlorate

Vlad: Thank you for the rapid turn around. We have addressed your comments in the attached document. Three issues I want to highlight are

- 1.
- 2.
- 3.

Ex. 5 Deliberative Process (DP)

We remain hopeful that this will address all concerns and that we can close out review ASAP tomorrow. I have copied April and Margo to facilitate that and have included Mary because Bill will be out of the office tomorrow.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Wednesday, May 22, 2019 7:29 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: Latest Comments on Perchlorate

Eric,

Attached please find what I hope to be our final comments on the perchlorate MCL NPRM and HRCCA. With the exception of a few minor technical edits, they are consistent with the items we have already discussed by phone. I think

Ex. 5 Deliberative Process (DP)

starting her review early. Either way, I'm hoping that we can review the documents very quickly in the morning and then give you the green light to begin the process of getting them prepared for signature while we take care of final administrative steps.

Please feel free to give me a call on my cell if you have any questions. If you don't already have it, my cell is

Ex. 6 Personal Privacy (PP)

Ex. 6 Personal Privacy (PP)

Good luck tonight!

Vlad

Message

From: Bradford, Charlotte [Bradford.Charlotte@epa.gov]
Sent: 4/18/2019 2:18:51 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Burneson, Eric [Burneson.Eric@epa.gov]
CC: Christ, Lisa [Christ.Lisa@epa.gov]
Subject: RE: Perchlorate briefing

The meeting is rescheduled -- 11:00 a.m., conference room 2339. Please proceed with notifying concerned parties.

-----Original Message-----

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]>
Sent: Thursday, April 18, 2019 10:16 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Bradford, Charlotte <Bradford.Charlotte@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Perchlorate briefing

Should I wait for confirmation that you were able to reschedule your 11 meeting or go ahead and notify reviewers that briefing has been moved to 11? Thanks again for doing this and sorry for inconvenience.

-----Original Message-----

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Thursday, April 18, 2019 8:35 AM
To: Bradford, Charlotte <Bradford.Charlotte@epa.gov>
Cc: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Christ, Lisa <Christ.Lisa@epa.gov>
Subject: Re: Perchlorate briefing

It was scheduled for 3 but we need to move it to 11. There is a Reg Det meeting at 11 that I need you to move please.

Sent from my iPhone

> On Apr 18, 2019, at 7:29 AM, Bradford, Charlotte <Bradford.Charlotte@epa.gov> wrote:
>
> Good morning, I need to confirm that the briefing is scheduled for Thursday, April 25, at 3.
>
> -----Original Message-----
> **From:** Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]>
> **Sent:** Wednesday, April 17, 2019 6:46 PM
> **To:** Burneson, Eric <Burneson.Eric@epa.gov>
> **Cc:** Christ, Lisa <Christ.Lisa@epa.gov>; Bradford, Charlotte <Bradford.Charlotte@epa.gov>
> **Subject:** Re: Perchlorate briefing
>
> That would be great thanks!! It also means that I would have a convenient excuse for a hard stop since I would have to leave to head to airport at 12:30.
>
> Sent from my iPhone
>
>> On Apr 17, 2019, at 6:22 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:
>>
>> Vlad
>> I am copying Charlotte to see if she can move a 11:00 meeting I have that day to make room for this meeting.
>> Charlotte can you please reply to all?
>>
>> Sent from my iPhone
>>
>>> On Apr 17, 2019, at 6:13 PM, Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)] wrote:
>>>
>>> Really sorry to do this but can we move the interagency briefing to Thursday morning? Just realize I 'll be in the air at 3:00. Had forgotten about a trip.
>>>
>>> Sent from my iPhone

Appointment

From: Dorjets, Vlad EOP/OMB Ex. 6 Personal Privacy (PP)
Sent: 4/18/2019 2:18:34 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]

Subject: Accepted: FW: Hold for Inter Agency Briefing on Proposed Perchlorate NPDWR
Location: DCRoomEast2339/DC-ICC-OW-OGWDW

Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Busy

Recurrence: (none)

Appointment

From: Jones, Lisa M. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 4/23/2019 8:38:57 PM
To: Mancini, Dominic J. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Theroux, Rich P. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Thomas, Amanda L. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Kluever, April N. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Glass, Jacob S. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Falk Curtin, Edna T. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Nickerson, William [Nickerson.William@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]
Subject: E.O. 12866 MTG re: National Primary Drinking Water Regulations: Regulation of Perchlorate (RIN 2040-AF28)
Location: Room 9258, New Executive Office Building (NEOB)/OMB - 725 17th Street, NW, Washington, DC 20503
Start: 4/30/2019 8:00:00 PM
End: 4/30/2019 8:30:00 PM
Show Time As: Tentative

Recurrence: (none)

This meeting was requested by the American Water Works Association.

Call-in: [Ex. 6 Personal Privacy (PP)] code [Ex. 6 Personal Privacy (PP)]

Here's the link for security information needed and the link may be shared: [Ex. 6 Personal Privacy (PP)]

Please include name as it shows exactly on driver's license or other government-issued identification to be used. Thank you.

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/15/2019 6:59:42 PM
To: Nickerson, William [Nickerson.William@epa.gov]
CC: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: RE: Perchlorate Passback Status

Fantastic!

From: Nickerson, William <Nickerson.William@epa.gov>
Sent: Wednesday, May 15, 2019 2:58 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Re: Perchlorate Passback Status

the intent is to pass back by COB today

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Wednesday, May 15, 2019 2:52 PM
To: Nickerson, William
Cc: Burneson, Eric
Subject: Perchlorate Passback Status

Bill,

Can you please let me know when you expect to send me the perchlorate passback? If we are to have to have any chance of meeting our aspirational deadline of next Thursday COB (to avoid working over memorial day weekend and to give you ample time to arrange for signature by Administrator Wheeler), I need to receive that passback by the end of the day. I have warned interagency reviewers that they will not be given a lot of time to review the revised documents but I have to be reasonable too. Margo, April and I need several days to review the documents too (and I know that Margo is also busy working on ACE). Would appreciate any insights on timing you could provide so that I can do what I can to prepare people.

Vlad

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 3/1/2019 3:06:02 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: RE: AWWA Meeting Request

I was really upset to miss the party but heard there was a good turn-out and that it went well. I'm sure Jim appreciate seeing you and all the OW folks he'd worked with for so lunch come out.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Thursday, February 28, 2019 4:35 PM

To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]

Subject: RE: AWWA Meeting Request

Sorry to have missed you at Jim's Retirement party. I appreciated the invitation and the opportunity to tell Jim how much I appreciated working with him over the years.

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)] >

Sent: Thursday, February 28, 2019 4:29 PM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Nickerson, William <Nickerson.William@epa.gov>

Subject: RE: AWWA Meeting Request

Thanks for the update. I'll start doing some background in preparation.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Thursday, February 28, 2019 4:26 PM

To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]

Cc: Nickerson, William <Nickerson.William@epa.gov>

Subject: RE: AWWA Meeting Request

Thanks Vlad: We are very much aware of the Clewell paper and evaluating its assessment of the modeling work we have done. Our plan is to move the package to OMB by the end of next week. Of course that requires a number of things to go right. I have copied Bill on my reply to keep him in the loop.

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)] >

Sent: Thursday, February 28, 2019 4:06 PM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Subject: FW: AWWA Meeting Request

Eric,

Hope you're doing well. So you know, we have turned down this meeting request and asked them to contact us when the rule is under review. I'm sure you're all over this paper but wanted to forward it to you anyway. Speaking of which, I assume you're pretty close to submitting this rule. Do you have a sense of when that will be? Note that my colleague Chad is currently having his weekly check-in with OP and I asked him to ask Bill the same thing.

Vlad

From: Kevin Morley <KMorley@awwa.org>

Sent: Thursday, February 28, 2019 3:14 PM

To: Theroux, Rich P. EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>; Schwab, Margo EOP/OMB
<[REDACTED] Ex. 6 Personal Privacy (PP)>; Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>; Echols, Mabel E. EOP/OMB
<[REDACTED] Ex. 6 Personal Privacy (PP)>

Cc: Steve Via <SVia@awwa.org>; Tracy Mehan <trmehan@awwa.org>

Subject: [EXTERNAL] AWWA Meeting Request

Mr. Theroux:

The American Water Works Association would like to meet with you and OIRA staff regarding recent findings related to EPA's Biologically Based Dose Response (BBDR) model for perchlorate (see attached).

We would like to meet with you on Friday, March 8 or Monday, March 11 if that is possible.

Thank you for your time and attention.

Kevin M. Morley, PhD

American Water Works Association
Manager, Federal Relations
1300 Eye Street, NW Suite 701W
Washington, DC 20005
D: 202-326-6124

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American Water Works Association
Dedicated to the World's Most Important Resource ®

Appointment

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 3/29/2019 1:57:36 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]

Subject: Accepted: Follow up on perchlorate
Location: call in [Ex. 6 Personal Privacy (PP)] code [Ex. 6 Personal Privacy (PP)]

Start: 3/29/2019 5:00:00 PM
End: 3/29/2019 5:30:00 PM
Show Time As: Busy

Recurrence: (none)

Message

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: 4/17/2019 9:11:00 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]
Subject: RE: Proposed Perchlorate NPDWR

Perfect, thanks.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Wednesday, April 17, 2019 4:23 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Vlad:
We can provide the requested support documents. The first document has been shared previously with many of the other Federal Agencies (see my email to Jim Kim on July 11, 2018) but we are happy to share this document again. It is attached to this email. The second document is currently under revision to incorporate some of the modifications we made just prior to submitting the proposed NPDWR. We expect to be able to send this document early next week.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: Tuesday, April 16, 2019 3:54 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Eric,

Kevin Bromberg has apparently already skimmed (if not actually read) the NPRM and is requesting two documents referenced in the preamble: the "proposed approaches to inform the derivation of a maximum contaminant level goal for perchlorate in drinking water" (reference 2018d) and the TSD (reference 2018e). Could you please let me know the status of these two documents? In case they're not currently available or will not be available soon it would help me to understand what they documents do and do not contain.

Vlad

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, April 16, 2019 1:10 PM
To: Dorjets, Vlad EOP/OMB <[REDACTED]> **Ex. 6 Personal Privacy (PP)**
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: Proposed Perchlorate NPDWR

Vlad

Thanks for touching base regarding the perchlorate proposed drinking water regulation. As we discussed I have blocked time on April 25 at 3:00 pm for a briefing to the other Federal Agency's on the perchlorate proposal. We will send an updated presentation to you early next week for distribution to the other Agency partners. I am assuming this will be a teleconference but let me know if you or other Federal partners would be interested in coming to EPA Offices for the meeting and I can book a larger room for the discussion.

As I mentioned I will be out of the office Thursday and Friday this week but if you have questions about the draft proposal you can contact Lisa Christ in my absence. Lisa's number is 202 564 8354.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 2/28/2019 9:05:54 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: FW: AWWA Meeting Request
Attachments: Clewell etal (2019) CIO4 BBDR Review RegToxPharm.pdf

Eric,

Hope you're doing well. So you know, we have turned down this meeting request and asked them to contact us when the rule is under review. I'm sure you're all over this paper but wanted to forward it to you anyway. Speaking of which, I assume you're pretty close to submitting this rule. Do you have a sense of when that will be? Note that my colleague Chad is currently having his weekly check-in with OP and I asked him to ask Bill the same thing.

Vlad

From: Kevin Morley <KMorley@awwa.org>
Sent: Thursday, February 28, 2019 3:14 PM
To: Theroux, Rich P. EOP/OMB <[Ex. 6 Personal Privacy (PP)]>; Schwab, Margo EOP/OMB <[Ex. 6 Personal Privacy (PP)]>; Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>; Echols, Mabel E. EOP/OMB <[Ex. 6 Personal Privacy (PP)]>
Cc: Steve Via <SVia@awwa.org>; Tracy Mehan <tmehan@awwa.org>
Subject: [EXTERNAL] AWWA Meeting Request

Mr. Theroux:

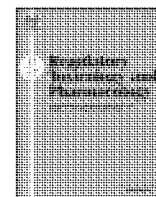
The American Water Works Association would like to meet with you and OIRA staff regarding recent findings related to EPA's Biologically Based Dose Response (BBDR) model for perchlorate (see attached).

We would like to meet with you on Friday, March 8 or Monday, March 11 if that is possible.

Thank you for your time and attention.

Kevin M. Morley, PhD
American Water Works Association
Manager, Federal Relations
1300 Eye Street, NW Suite 701W
Washington, DC 20005
D: 202-326-6124

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Commentary

An evaluation of the USEPA Proposed Approaches for applying a biologically based dose-response model in a risk assessment for perchlorate in drinking water



Harvey J. Clewell III^{a,*}, P. Robinan Gentry^b, C. Eric Hack^c, Tracy Greene^b, Rebecca A. Clewell^d

^a Ramboll US Corporation, Research Triangle Park, NC, USA

^b Ramboll US Corporation, Monroe, LA, USA

^c ScitoVation, Research Triangle Park, NC, USA

^d ToxStrategies, Research Triangle Park, NC, USA

ARTICLE INFO

Keywords:

Perchlorate

Risk assessment

MCLG

BBDR model

ABSTRACT

The United States Environmental Protection Agency's (USEPA) 2017 report, "Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water", proposes novel approaches for deriving a Maximum Contaminant Level Goal (MCLG) for perchlorate using a biologically-based dose-response (BBDR) model. The USEPA (2017) BBDR model extends previously peer-reviewed perchlorate models to describe the relationship between perchlorate exposure and thyroid hormone levels during early pregnancy. Our evaluation focuses on two key elements of the USEPA (2017) report: the plausibility of BBDR model revisions to describe control of thyroid hormone production in early pregnancy and the basis for linking BBDR model results to neurodevelopmental outcomes. While the USEPA (2017) BBDR model represents a valuable research tool, the lack of supporting data for many of the model assumptions and parameters calls into question the fitness of the extended BBDR model to support quantitative analyses for regulatory decisions on perchlorate in drinking water. Until more data can be developed to address uncertainties in the current BBDR model, USEPA should continue to rely on the RfD recommended by the NAS (USEPA, 2005) when considering further regulatory action.

1. Introduction

From a regulatory perspective, the critical effect of concern from exposure to perchlorate is disruption of thyroid function and the potential for thyroid-hormone-related effects on neurodevelopment in gestation; these effects represent downstream events resulting from competitive inhibition of iodide uptake by the perchlorate ion (USEPA, 2002). Based on an analysis of the mode of action for perchlorate, the United States Environmental Protection Agency (USEPA) (2002) determined that inhibition of thyroid iodide uptake could be used as an obligatory precursor for these critical effects in a harmonized cancer/noncancer risk assessment for perchlorate (Fig. 1). This mode-of-action directed risk assessment approach was used in the derivation of the current Reference Dose (RfD) for perchlorate of 0.0007 mg/kg/day (USEPA, 2005). Following the recommendations of the National Academy of Sciences National Research Council (NRC) (2005), the point of departure (POD) for this RfD was a reported No Observed Effect Level (NOEL): a non-statistically significant mean of 1.8%

(standard error of the mean 8.3%) decline in radioactive iodine uptake (RAIU) in healthy adults following two weeks exposure to a daily perchlorate dose of 0.007 mg/kg/day (Greer et al., 2002). An intraspecies uncertainty factor of 10 was applied to protect the most sensitive population, the fetuses of pregnant women who might have hypothyroidism or iodide deficiency.

Subsequently, the USEPA Office of Drinking Water (2008) published an Interim Health Advisory Level for perchlorate of 15 µg/L, based on the USEPA (2005) RfD of 0.7 µg/kg/day, as recommended by the NRC (2005). Determination of this Interim Health Advisory Level considered Physiologically-Based Pharmacokinetic (PBPK) Modeling (Clewell et al., 2007) to estimate the potential effect of perchlorate on iodide uptake in several sensitive subgroups, including the pregnant woman and fetus, the lactating woman and neonate, and the young child. Despite widespread scientific acceptance of iodide inhibition as an obligatory precursor to downstream toxicity endpoints, there was remaining concern regarding the level of protection for the population perceived to have the greatest susceptibility – the fetuses of

* Corresponding author.

E-mail address: hclewell@ramboll.com (H.J. Clewell).

<https://doi.org/10.1016/j.yrtph.2019.01.028>

Received 19 October 2018; Received in revised form 18 January 2019; Accepted 20 January 2019

Available online 29 January 2019

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(<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

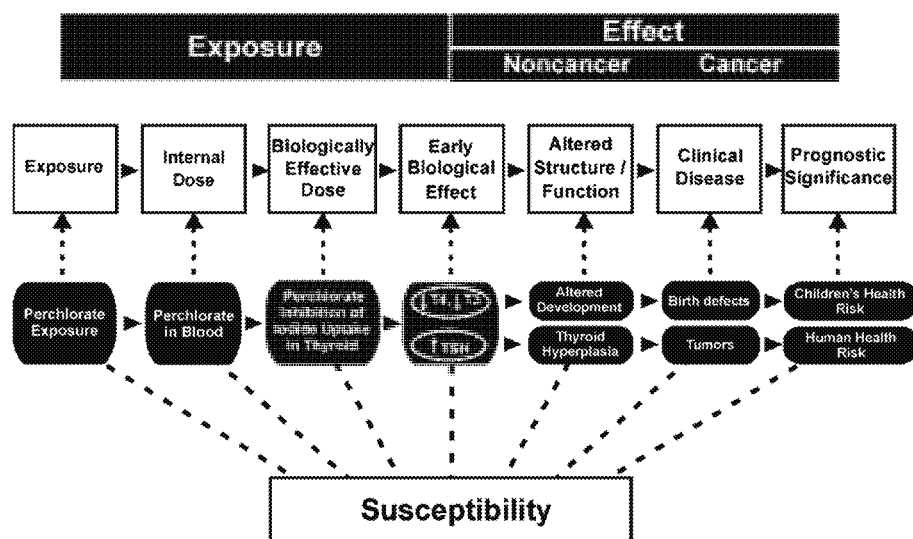


Fig. 1. Mode-of-action model for perchlorate toxicity proposed by the USEPA (2002). Inhibition of iodide uptake in the thyroid by perchlorate is an obligatory precursor for all downstream cancer and noncancer endpoints, including neurodevelopment.

hypothyroid mothers.

Over the next several years, the focus of research on perchlorate shifted to the development of a biologically based dose-response (BBDR) model of the hypothalamic-pituitary-thyroid (HPT) axis that could be linked with the PBPK model of perchlorate and iodide to predict dose-dependent interactions of perchlorate with iodine hormone homeostasis as a function of iodide intake in an effort to more quantitatively account for the effects of low dietary iodide intake and hypothyroidism in pregnant women on fetal development (McLanahan et al., 2008, 2009; Fisher et al., 2012; Lumen and George, 2017a, 2017b; Lumen et al., 2013, 2015).

The USEPA Science Advisory Board ((SAB 2013)) report on perchlorate in drinking water supported the utility of BBDR modeling to help characterize the potential for neurological effects from perchlorate exposure:

“As perchlorate research continues, studies in animals may provide important insights into the neurobehavioral consequences of perchlorate exposure. A physiologically-based pharmacokinetic/pharmacodynamic framework is well suited to help place these findings in the context of human perchlorate exposure.”

The USEPA SAB (2013) identified a number of areas for improvement or modification of the existing models. However, they also noted that “Models can always be improved, but the goal is to have a model that is fit for the intended purpose.”, apparently cautioning against perpetual model refinement at the expense of implementation, echoing the concern of the renowned statistician, George E.P. Box, who famously used to say: “All models are wrong but some are useful” (Box, 1976).

Recently, the USEPA's Office of Ground Water and Drinking Water (USEPA, 2017) responded to the Science Advisory Board recommendations and proposed novel approaches to inform the derivation of a Maximum Contaminant Level Goal (MCLG) for perchlorate, including the use of BBDR modeling in their report entitled “Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water”. This MCLG approach (USEPA, 2017) includes revisions to a previously developed and peer reviewed BBDR model (McLanahan et al., 2008, 2009; Fisher et al., 2012; Lumen and George, 2017a, 2017b; Lumen et al., 2013, 2015) that was extended to predict the relationship between perchlorate exposure and thyroid hormone levels in sensitive life stages. These revisions aim to address suggestions by the USEPA SAB (2013),

including the following:

- Derivation of a perchlorate MCLG that addresses sensitive life stages through PBPK/PD modeling;
- Expansion of the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure;
- Utilization of a mode of action framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition to thyroid hormone changes and finally neurodevelopmental impacts; and
- Extension of “the [BBDR] model expeditiously to...provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages” (USEPA SAB, 2013, p. 19).

Model revisions presented in the USEPA (2017) report include: incorporating a description of the physiology of early pregnancy, biological feedback control of hormone production via thyroid-stimulating hormone (TSH) and human chorionic gonadotropin (hCG), and a description of the response to lower levels of iodide nutrition. In addition, an attempt was made to calibrate the model's behavior for upper and lower percentiles of the population, in addition to the population median, for thyroid hormone production. The report also included an uncertainty analysis for key BBDR model parameters.

For the development of the MCLG, USEPA (2017) proposed a two-stage approach linking the revised BBDR model results (“Stage 1”) with quantitative information on neurodevelopmental outcomes from epidemiological studies (“Stage 2”). Stage 1 describes the thyroidal hormone levels in women of childbearing age with low to adequate iodide intake. In this stage, the revised BBDR model is applied to predict the relationship between perchlorate exposure and changes in thyroid hormone levels in early pregnancy. Data for Stage 2 of the approach is provided from epidemiological studies evaluating maternal thyroid hormone levels in early pregnancy and the relationship between changes in these levels and the observation of neurodevelopmental outcomes. The USEPA (2017) report also described development of a novel population-based approach that uses the revised BBDR model to estimate changes in levels of selected thyroid hormones, specifically free tetraiodothyronine (fT4) and TSH, resulting from perchlorate exposure that may result in an increase in the prevalence of

hypothyroxinemia in pregnant women. Hypothyroxinemia (low circulating concentrations of fT4) is often associated with hypothyroidism (low concentrations of fT4 despite increased concentrations of TSH).

The evaluation and (potential) application of the perchlorate BBDR model will serve as an important precedent for future consideration of such models by the agency, as it is only the second such model to be seriously evaluated by USEPA and subjected to external peer-review. The first BBDR model to be considered, formaldehyde nasal carcinogenicity developed by Conolly and colleagues (2003, 2004), has been under consideration by the agency for more than a decade. Interest in the use of BBDR modeling in risk assessment peaked in the 1990s when the draft USEPA (2003) Cancer Guidelines identified these models as the preferred option for performing a cancer dose-response. However, since that time, work in this area has waned, possibly due to the perceived difficulty of gaining regulatory acceptance. By their nature, BBDR models are descriptions of complex biological systems that necessarily include significant uncertainty. The challenge going forward will be to develop approaches for characterizing that uncertainty in a risk assessment context and ensuring that these complex models are fit for their intended purpose. It is with this consideration in mind that we have performed a focused evaluation of the proposed USEPA (2017) approaches.

Our critical review focused on two key areas of importance for determining whether the current BBDR model is fit for the purpose of supporting regulatory decisions based on predicted effect of perchlorate exposure on human fetal development:

1. Evaluation of USEPA (2017) model revisions to the peer reviewed BBDR models, including extending the model to early pregnancy, incorporating biological feedback control of hormone production via thyroid stimulating hormone (TSH) and human chorionic gonadotropin (hCG) signaling, calibration of the model for thyroid hormone effects, and uncertainty analysis for key parameters. This evaluation included comparison of model output to results from key human studies identified in previous assessments (Greer et al., 2002, Braverman et al., 2006, Téllez Téllez et al. (2005a, 2005b), as well as in the USEPA (2017) document (Steinmaus et al., 2016);
2. Evaluation of USEPA (2017) approaches for linking BBDR results to neurodevelopmental outcomes and identification of published literature to develop the quantitative relationship between thyroid hormone levels and neurodevelopmental outcomes; and

After describing the results of this evaluation, we present a comparison of the results from the USEPA (2017) approach with results from previous USEPA assessments, in order to put the uncertainties in the BBDR approach in perspective against the potential impact of the new approach on the existing regulatory guidelines for perchlorate USEPA (2005, 2008).

2. Methods

Evaluating Stage 1 of USEPA MCLG approach: Stage 1 of USEPA's MCLG approach relies upon the application of the BBDR model to predict the effect of perchlorate on the thyroid hormone in pregnant women at different iodine nutrition levels, with the goal of predicting fT4 hormone reduction in pregnant women with low dietary iodide. To evaluate the utility of the proposed model to support such predictions, we independently ran the model and tested model predictions against data from multiple studies. These exercises attempted to both duplicate BBDR model results for datasets that were used by USEPA (2017) to calibrate the model and to test the ability of the BBDR model to predict the well-described precursor event inhibition of iodide uptake, which was successfully described with previous versions of the perchlorate PBPK models (Merrill et al., 2003; Clewell et al., 2007). These simulations included:

Steinmaus et al., (2016) – cross-sectional epidemiological study evaluation of serum and urine in pregnant women in California: used in USEPA (2017) to evaluate BBDR model predictions of perchlorate effects on fT4 and TSH

Greer et al., (2002)–14-day controlled perchlorate dose study in male and female adults in the US: used in USEPA (2017) to estimate urinary clearance parameters in BBDR model

Braverman et al., (2006) – 6-month controlled perchlorate dose study in male and female adults: not used in USEPA (2017).

Téllez Téllez et al., (2005a), 2005b – longitudinal epidemiological study in pregnant and lactating women in Chile: used in USEPA (2017) to estimate urinary clearance parameters in BBDR model

In our efforts to produce these simulations, it was noted that instructions provided in the USEPA documentation for running the model for different scenarios, and documentation of the rationale for the model parameter values associated with them, are often inadequate and lack transparency; this deficiency is exacerbated by the number of permutations of parameter settings used in the scripts that generate the results in the document. The complexity of the BBDR model makes it difficult to perform this evaluation, even though it has been conducted by experienced modelers.

Evaluating Stage 2 of USEPA MCLG approach: Stage 2 of USEPA's approach involved evaluating the published epidemiological literature to identify publications that would define quantitative relationships between thyroid hormone levels and neurodevelopmental effects. The USEPA approach was focused on the identification of studies that provided information on levels of fT4 in pregnant mothers during early gestation and the potential for changes in neurodevelopmental outcomes in their offspring. Through targeted literature searching and recommendations from the Science Advisory Board (SAB), a total of 55 studies were identified by USEPA to provide information on altered maternal thyroid hormone levels and offspring development. These studies were divided into three groups to facilitate evaluation:

Group 1 – studies that may be able to quantitatively describe a relationship between incremental alterations in maternal thyroid hormone levels and alternations in offspring development;

Group 2 – studies that do not have data from which to derive a quantitative relationship between maternal hormones and offspring neurodevelopment, but instead present only a categorical analysis with thyroid hormones below and above a defined cut point and adverse neurodevelopmental outcomes; and

Group 3 – studies that present an analysis that is not directly compatible with BBDR output.

Of the 55 studies, 15 were identified as Group 1, 14 were identified as Group 2, 26 were identified as Group 3. The 15 Group 1 studies were then evaluated further and only 5 were deemed useful by the USEPA for further quantitative analysis to attempt to connect alterations in thyroid hormone levels to alterations in neurodevelopment. In our evaluation, we performed a critical review of the USEPA Stage 2 approach and the study summaries provided in USEPA (2017), considering the most recent recommendations from the National Research Council (NRC, 2014) on systematic review of the literature and evidence integration.

3. Results

3.1. Evaluation of the perchlorate BBDR model for early pregnancy

The draft MCLG approach (USEPA, 2017) is based on a hypothesized mode of action (Fig. 1) for neurodevelopmental outcomes resulting from development of hypothyroxinemia from perchlorate-induced inhibition of iodide uptake in the thyroid. As noted in USEPA (2017):

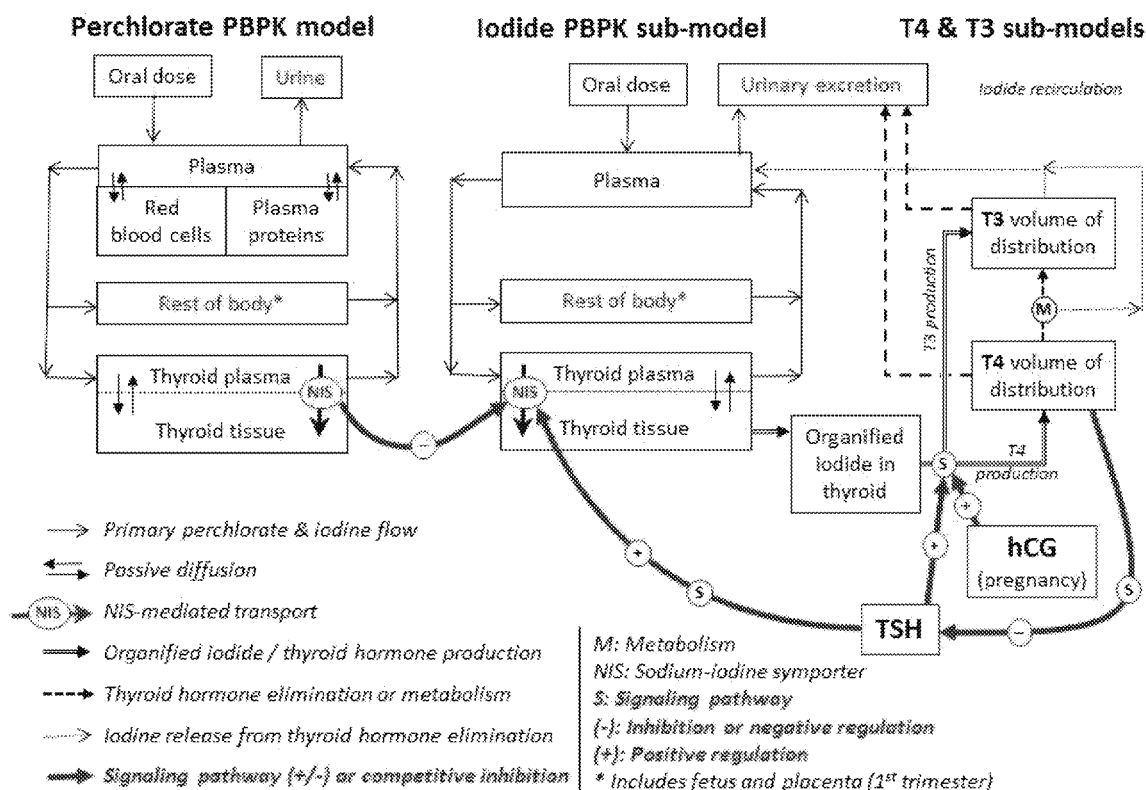


Fig. 2. Structure of the early pregnancy BBDR (USEPA, 2017).

“Thyroid hormones are essential for the development and differentiation of the developing brain. The brain and spinal cord begin development in the first half of the first trimester. fT4 passes through the blood-brain barrier via multiple, specific transporter proteins. Next, T4 is converted to T3 by the developing glial cells and then transported to neurons. T3 then interacts with nuclear receptors to tightly regulate gene expression so that neurogenesis, synaptogenesis, neuronal migration, cell differentiation, and myelination are developmentally appropriate. Deficiencies in thyroid hormones through iodine deficiency, congenital hypothyroidism, or maternal hypothyroidism/hypothyroxinemia can result in neurological impairments and intellectual deficits (Morreale de Escobar, Obregón, & Escobar del Ray, 2000).”

As recommended by the USEPA SAB (2013), the USEPA extended a published BBDR model for perchlorate induced hypothyroxinemia in late gestation (Lumen et al., 2013; Lumen and George, 2017a, 2017b) to address the sensitive population of concern for exposure to perchlorate: the fetuses of hypothyroxinemic women during early pregnancy (Fig. 2). These concerns were motivated by new studies (Steinmaus et al., 2016), suggesting an association between perchlorate exposure and decreased levels of free thyroxine (fT4) in pregnant women. Because the fetus is entirely dependent on maternal thyroid hormones for neurodevelopment in early gestation (Clewell et al., 2007; Howdeshell, 2002), the endpoint of interest was defined as reduction in maternal fT4 in early pregnancy and the perchlorate BBDR models were extended to describe hormone homeostasis during gestation. Expansion of the original models of perchlorate and iodide (Clewell et al., 2007) to predict the impact of perchlorate exposure on fT4 during early pregnancy, however, is complicated by the significant variability in the levels of fT4 in the general population and the challenges in measuring fT4, as well as the dynamics of changing hormones through the course of gestation and the uncertainty in identifying the level of alteration that may lead to hypothyroidism and fetal effects.

According to the “American Thyroid Association Task force on

Thyroid Disease During Pregnancy and Postpartum”, isolated hypothyroxinemia is defined as a normal maternal TSH concentration in conjunction with fT4 concentrations in the lower 5th or 10th percentile of the reference range (Stagnaro-Green et al., 2011). USEPA (2017) has also focused on selected percentiles of the reference range; however, reference ranges can vary from population to population according to the 2017 Guidelines of the American Thyroid Association for the Diagnosis and Management of Thyroid Disease During Pregnancy and Postpartum (Alexander et al., 2017). Even within US populations and across ethnic groups, the 2.5th percentile can vary by up to 2 pmol/L or approximately 20% (9.3–11.4 pmol/L as reported by Alexander et al., 2017).

The variation in fT4 reported in the published literature during early pregnancy is provided in USEPA (2017), Appendix A, Figure A-33 and reproduced in Fig. 3. The levels of fT4 during early pregnancy, based on the studies identified by USEPA (2017), appear to range from

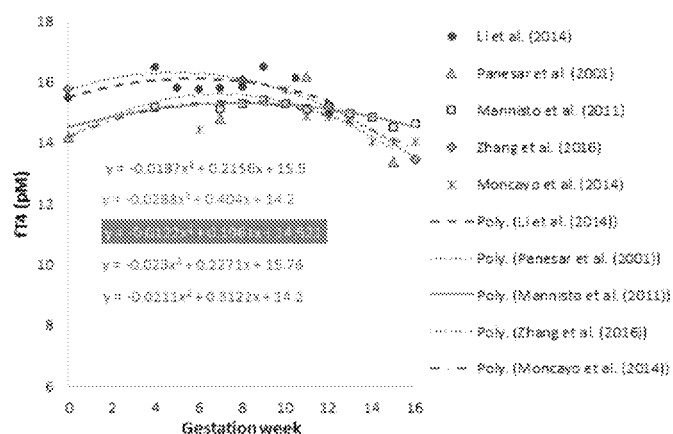


Fig. 3. Variation in free T4 (fT4) in early pregnancy (as reported in USEPA, 2017)) (Li et al., 2014; Männistö et al., 2011; Moncayo et al., 2015; Panesar et al., 2001; Zhang et al., 2016).

approximately 13–17 pmol/L. This range is consistent with the range of baseline fT4 means reported in the Greer et al. (2002) study of approximately 1.1–1.3 ng/dL (14–17 pmol/L). However, the 50th percentile BBDR model predictions at zero dose perchlorate and 170 µg/day iodine intake are approximately 10 pmol/L at gestation weeks 12, 13, and 16, considerably below these reported values.

Measuring fT4 in the presence of high concentrations of bound T4 is challenging, especially in conditions where binding proteins are altered such as during pregnancy (Alexander et al., 2017). Measurement techniques are prone to inaccuracy during pregnancy due to disruption of the original equilibrium. The 95% fT4 reference intervals decrease gradually with advancing gestational age: from 1.08 to 1.82 ng/dL (approximately 13.9–23.5 pmol/L) in week 14 to 0.86–1.53 ng/dL (approximately 11.1–19.8 pmol/L) in week 20 (Alexander et al., 2017).

Extending the thyroid BBDR model to address early gestation is particularly challenging due to the complex interaction between thyroid homeostasis and gestational development. Considering the addition of TSH feedback dynamics, and an adjustment factor to match specific population percentiles, there is reason for concern regarding the uncertainty of the revised model predictions under low iodide intake conditions. Some of these concerns are highlighted below:

Description of hCG dynamics: Human chorionic gonadotropin (hCG) levels rise in early pregnancy and this in turn increases both sodium-iodide symporter (NIS) uptake activity and T4 production. hCG is structurally similar to TSH and, like TSH, increases thyroidal iodide uptake and thyroid hormone synthesis by binding to the thyroid-stimulating hormone receptor (TSHR) (Hoermann et al., 1994). In the model, hCG levels are calculated as a function of gestational age, using an equation for the parameter HCGREG (Fig. 4, purple curve), and these changing levels are used to increase the rate of T3 and T4 production as a function of the hCG concentration:

$$\text{HCGreg} = 1 + 0.00354 \times \text{hCG}$$

The variation of hCG over the duration of gestation is based on direct measurements of hCG in pregnant women (Korevaar et al., 2015). However, the concurrent increase in thyroidal iodine uptake is described in the model based on an empirical relationship between gestational age in weeks (GW) and radioactive iodide uptake, using an equation for the parameter VCHNG (Fig. 4, green curve):

$$\text{VCHNG}(\text{GW}) = 1 + 0.076\text{GW} - 0.0025\text{GW}^2$$

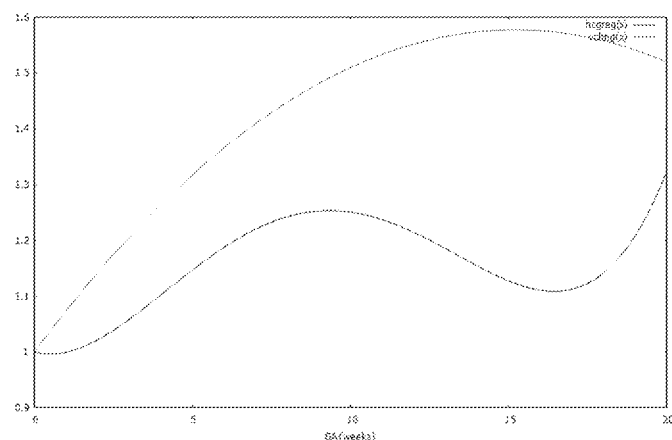


Fig. 4. Comparison of parameters controlling hCG-dependent changes in thyroidal uptake (VCHNG, green) and thyroid hormone production rate (HCGREG, purple) in the BBDR model as a function of gestational age. Despite the fact that both parameters are dependent upon hCG levels, the predicted trends across gestation are not consistent. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

Thus the model does not correctly attribute the gestational control of NIS uptake to hCG, when in fact both uptake and hormone synthesis respond to the same changes in hCG (Pesce and Kopp, 2014). By using different equations for the time-dependence of hCG-stimulated uptake and hormone production (Fig. 4) the model decouples processes that are fundamentally linked by their biology. Fig. 4 depicts the time-course of the parameters controlling changes in iodide uptake (VCHNG) and hCG hormone levels (HCGreg) over the course of gestation. While the biology indicates a proportional relationship between the two parameters, the equations used in the model are not parallel. Elucidating the impact of this decoupling is challenging, and is beyond the scope of this review, since it would have to be investigated at a large number of time-points throughout pregnancy and under different conditions of iodine intake, but the disparity between the model description and the underlying biology justifies caution regarding its predictions of T4 and TSH at different gestational ages, as these parameters govern hormone production and release. We address the impact of the discrepancy between the time-courses for HCGREG and VCHNG in a later section.

3.1.1. Damping of TSH response

The USEPA (2017) BBDR model includes a parameter, pTSH (power to which the ratio of current TSH to the TSH set-point is raised), that reduces the response of the thyroid to increases in TSH:

$$\text{TSHreg} = (\text{TSH}/\text{TSH}_0)^{\text{pTSH}}$$

Using this equation, a pTSH exponent of 0 would represent no control of thyroid function by TSH and an exponent of 1 would represent a linear response of thyroid function to changes in TSH. In their calculations of the effect of perchlorate on the prevalence of hypothyroxinemic pregnant women, the USEPA (2017) use a pTSH exponent of 0.398, which results in a response to TSH that is substantially less than linear, an assumption that is inconsistent with the fundamental biological relationship between TSH and thyroid hormones (production and release of T3 and T4), effectively decoupling a relationship that has been well established in the medical, pharmacological and toxicological communities. USEPA (2017) describes the rationale for this parameter: “The NHANES data do not show a clear correlation between TSH and fT4, so within that data set they vary independently. One could assume, therefore, that individuals with an average fT4 and high TSH have that combination because their thyroid has a weak response to TSH, and vice-versa.” To address this concern, USEPA (2017) estimated a lower and upper bound for pTSH as (median TSH)/(97.5th percentile TSH) = 0.398 and (median TSH)/(2.5th percentile TSH) = 3.09, respectively, with a median value of pTSH = 1. Thus, this parameter is used to attempt to represent disease states where the individual's thyroid is either exquisitely sensitive or insensitive to TSH stimulation. At lower values, this parameter reduces the impact of TSH on the Vmax for thyroid iodide uptake as well as the rate constants for T4 and T3 production in the thyroid. However, the USEPA (2017) also states that: “The coefficient, pTSH, is included...to allow for tuning of the strength of the TSH feedback, but in practice model simulations versus data appear quite adequate with pTSH = 1.” Concerns about this parameter are two-fold. First, the complexity of the model and various runtime scripts makes it nearly impossible to determine the use of this parameter during some of the model assessment and risk assessment simulations presented in USEPA (2017). Second, using point estimate population level data to define the quantitative temporal relationship between two fundamentally linked processes at the individual level is scientifically inappropriate. To understand the biological feedback within a single individual (i.e. to determine the relationship of TSH to T3/T4 and Vmax for a hypothyroid or hyperthyroid individual), matched samples would be needed for TSH, T3 and T4. This information – to our knowledge – is not available from NHANES. Thus, the epidemiological point estimate data are being used

well beyond its domain of applicability to predict the quantitative outcome of disease states.

3.1.2. Calibration of hormone production rates

The model uses a baseline first-order constant calibrated to NHANES 2007–2012 median, 10th, or 90th percentile non-pregnant data (fT4, fT3, T4 and T3 concentrations). The model parameter for the rate of production of T4 (KProdT4F) for the median NHANES calibration used in USEPA (2017) is 6.25×10^{-7} /hr/kg^{0.75} (their Table A-2), which is 4-fold lower than the value of 2.45×10^{-6} estimated for the published model (Lumen et al., 2013), which was based on the data of Nicoloff et al. (1972). However, the use of a T4 production rate that is lower than the published value is not adequately justified, given the importance of this parameter, which has a direct impact on predictions of fT4 changes, the intended application of the model. This baseline value is then scaled in pregnancy through GW 16 (peak occurring ~ GW 9) based upon placental hCG increase over this time, according to the linear relationship from Glinoeir (1997): hCGreg = 1 + 0.00354 × hCG.

3.1.3. Affinity of NIS iodine uptake

The model uses a Km for perchlorate binding to the NIS (KmNIS.P) that is 3-fold lower than the value estimated by Lumen et al. (2013) (i.e. a 3-fold higher affinity). Specifically, the new Km represents the 2.5th percentile lower confidence limit of the population median based upon the USEPA (2017) reanalysis of Greer et al. (2002). The median value (50th percentile = 0.73 μM) is similar to that obtained from a re-analysis of *in vitro* binding data, 0.59 μM (Schlosser, 2016); the use of a value of KmNIS.P = 0.489 μM makes perchlorate 3 times more effective at competitive inhibition of NIS compared to the model of Lumen et al. (2013). This revision to the Km in USEPA (2017) necessitated revisions to the Vmax (VmaxNISF_thy.P) and urinary excretion parameters (CLFUP) (Table 1 of USEPA, 2017), further affecting the model's sensitivity to changes in perchlorate dose, particularly under conditions of low iodide. Thus, The USEPA (2017) BBDR model predicts much greater effects of perchlorate on iodide uptake than any previous version of the model, without justification for re-estimating these parameters rather than using the published values.

3.1.4. Assumptions regarding thyroidal iodide storage

Plots of NHANES 2007–2012 data for non-pregnant women demonstrated little relationship between iodine intake and fT4, even at iodide intake levels below 75 μg/day (Figure A-54 of USEPA, 2017; reproduced in Fig. 5a). USEPA (2017) used data on the relationship between thyroidal iodide stores (mg) and iodine intake from Delange (2000), which assumes depletion of fT4 at iodide intake levels below 100 μg/day. As is clear from Fig. 5b, this assumed model behavior at concentrations below 100 μg/day, which drives model predictions at low intakes, is inconsistent with the NHANES data and could result in overprediction of fT4 responses at moderately low intakes of iodide, including the ranges simulated in the USEPA report. This possibility was investigated in this evaluation and the results are discussed in the next section.

Table 1

Simulation of the Greer et al. (2002) perchlorate study.

Dose	RAIU (%)		fT4 (pM)	
(μg/kg/d)	Simulated	Measured	Simulated	Measured
0	100	100	10.33	–
7	89	98.2	10.33	–
20	74	83.6	10.32	16.09
100	37	55.3	10.31	15.26
500	11	32.9	10.30	15.44

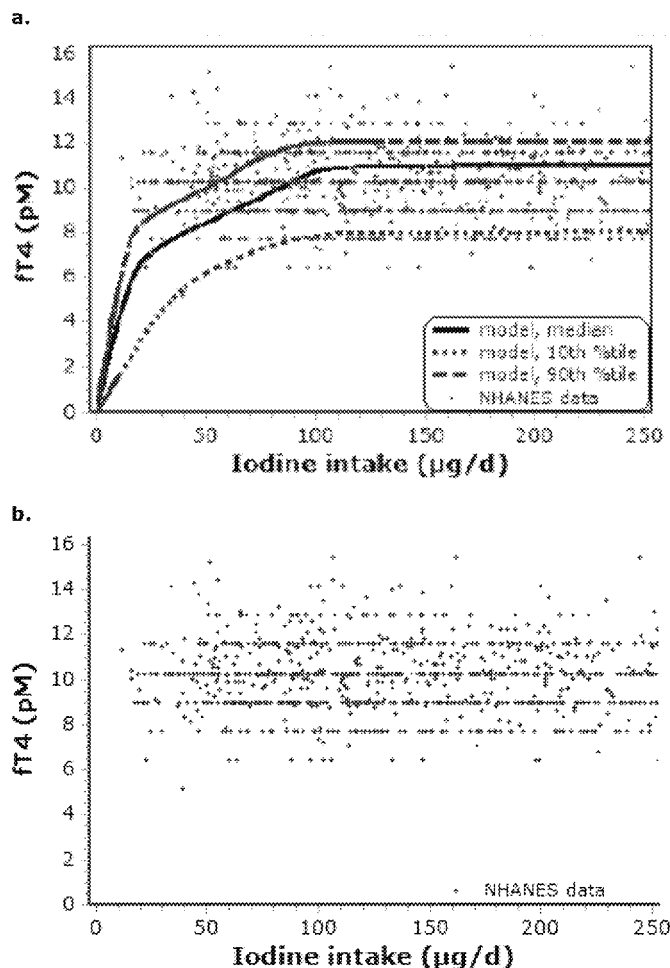


Fig. 5. Panel a: Model predictions for free T4 (fT4) in non-pregnant women as a function of iodine intake compared to data from NHANES 2007–2012 (USEPA, 2017). Panel b: Underlying NHANES data without model predictions. Note the lack of evidence for any correlation between iodine intake and fT4 in the NHANES data in the range from 20 to 90 μg/d, in contrast to model predictions.

3.2. Evaluation of BBDR model behavior

3.2.1. Comparison to the Steinmaus et al., (2016) results

In Appendix B of USEPA (2017), a comparison of the predicted changes in both fT4 and TSH from the BBDR model were compared to the results reported by Steinmaus et al. (2016). The Steinmaus et al. (2016) study was conducted to evaluate the potential for perchlorate exposure to impact thyroid hormone levels in pregnant women (any trimester) in San Diego. They reported an effect of perchlorate on fT4 levels to be similar among women with both low iodine (< 100 μg/day) and normal (100–300 μg/day), with a greater effect of perchlorate observed among pregnant women in the high iodine intake group (> 300 μg/day). They further noted that this result is in contrast to some previous results from NHANES (Blount et al., 2006) and may be due to the overall iodine sufficiency in the studied population or the fairly long time between urine iodine and serum thyroid hormone sample collection (about 9 weeks).

The comparison of the predicted fT4 changes from the BBDR model and the Steinmaus et al. (2016) results associated with changes in perchlorate dose are reported in Figure B-1 of Appendix B of USEPA (2017) and reproduced in Fig. 6. This comparison, which we were able to reproduce using the USEPA (2017) BBDR model, clearly highlights the differences between the model predictions and the published human data. The USEPA (2017) BBDR model simulations with normal iodine intake (170 μg/day) demonstrate no change in fT4, which is

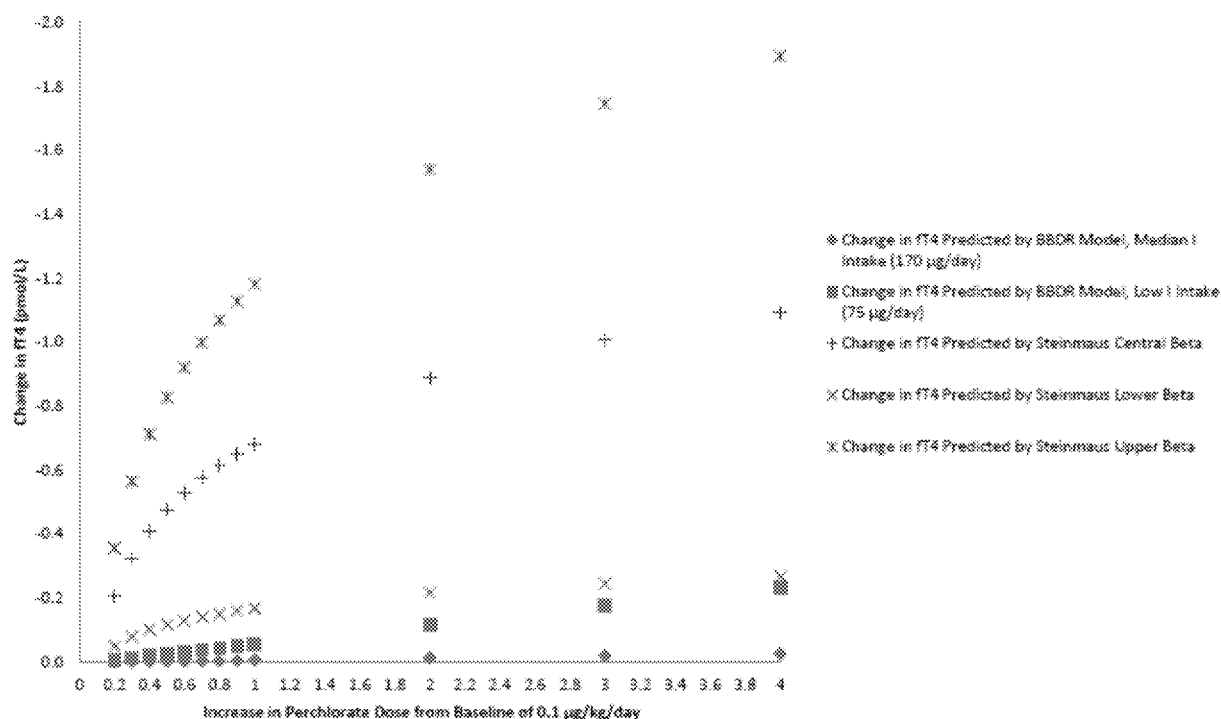


Fig. 6. Comparison of BBDR model predicted free T4 (fT4) changes as a function of perchlorate dose with data from Steinmaus et al. (2016). Reproduced from USEPA (2017). Blue boxes and diamonds represent the BBDR model predictions for median (170 µg/d) and low (90 µg/d) iodine intake populations (GW 13–16); red '+'s represent the central estimate from the analysis of the Steinmaus et al. (2016) study and the red x's represent the upper and lower confidence limits for that estimate. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

consistent with other studies in which no impact on fT4 has been observed at doses up to 7 µg/kg/day perchlorate (Greer et al., 2002; Braverman et al., 2006). The USEPA (2017) BBDR model greatly under-predicts the changes in fT4, even in the scenario with low dietary iodine intake (75 µg/day), in comparison to the changes reported by Steinmaus et al. (2016). This discrepancy raises concerns about the ability of the USEPA (2017) BBDR model to predict changes in fT4 associated with chronic perchlorate exposure during pregnancy.

3.2.2 Greer et al., (2002)–14 day human controlled perchlorate dosing study

The Greer et al. (2002) study was conducted to establish the dose-response in humans for perchlorate inhibition of thyroidal iodide uptake and any short-term effects on thyroid hormones following exposure for male and female volunteers to perchlorate in drinking water at doses of 7, 20, 100 or 500 µg/kg/day for 14 days. The results of this study have previously been relied upon by the USEPA (2005) to derive a reference dose (RfD) and to determine health reference levels (HRLs). The results of this study indicate a decrease in iodide uptake following exposure to a dose of 20 µg/kg/day, but no effect on hormone levels, including fT4 and TSH, at the highest dose tested. A No Observed Effect Level (NOEL) of 7 µg/kg/day was determined based on these results, and an RfD of 0.7 µg/kg/day was adopted, based on NAS recommendations, with the application of an uncertainty factor of 10 for intraspecies variability or sensitive subpopulations.

Consistent with the results of the study, our simulations of the adult exposures reported in Greer et al. (2002) with the BBDR model (Table 1) indicated no significant change in fT4 at doses up to 500 µg/kg/day. However, predicted concentrations of fT4 are lower than those measured by Greer et al. (2002). The model simulation reported in Table 1 was run with an iodine intake of 90 µg/day, as this was the value USEPA (2017) used in the Greer_test.m script provided with the BBDR model code. However, 90 µg/day is not consistent with the 170 µg/day value USEPA (2017) reports as representing a sufficient intake and USEPA's (2017) documentation does not indicate why a lower

value was used for the individuals in the Greer study. Simulation of iodide uptake inhibition (RAIU) appears to over-predict the reduction in uptake compared to measured values, though the qualitative increasing trend of inhibition with dose behaves appropriately. This discrepancy may result from the low iodine intake chosen by USEPA (2017), or a number of other decisions made in the model revisions, including the reduced Km parameter value. It is unclear why the parameters governing iodide inhibition were altered from previous models that successfully predicted inhibition of iodide in human subjects (Clewell et al., 2007; Merrill et al., 2003; Lumen et al., 2013). Given that iodide inhibition is the obligatory precursor to all downstream effects in the USEPA's proposed mode of action for perchlorate, it would be expected that any changes to the model that lead to reduced accuracy in the prediction of iodide inhibition would be accompanied by substantial support. However, no such support is provided in USEPA (2017) for the changes in the key parameters and the resulting effect on iodide inhibition predictions.

3.2.3 Braverman et al., (2006)–6 month human controlled perchlorate dosing study

The Braverman et al. (2006) study was conducted to determine whether prolonged exposure (6 months) of adults to low levels of perchlorate (0.5, 1.0 or 3.0 mg/day) would perturb thyroid function. The study included a small number of individuals (n = 13); however, iodine levels were comparable with those of the general population. The authors noted the limitations of the small sample size, but concluded that the results suggested that healthy, euthyroid individuals, with normal levels of iodine intake, can tolerate chronic exposure to perchlorate at doses of up to 3 mg/day (approximately 40 µg/kg/day) without any effects on thyroid function, including inhibition of iodine uptake.

The Braverman et al. (2006) study was simulated as part of the current evaluation using the BBDR model and predicted T3 and TSH levels were compared to the reported measurements (Table 2). fT4 was

Table 2
Simulation of Braverman et al. (2006) perchlorate study.

Dose ($\mu\text{g}/\text{kg}/\text{d}$)	T3 (nM)		TSH (mIU/L)	
	Simulated	Measured	Simulated	Measured
0	2.63	2.49	1.51	1.20
7	2.63	2.51	1.52	1.60
43	2.62	1.77	1.53	2.60

not compared because it was not clear how to convert the T4 index reported in the study to a concentration and vice versa. As with the Greer et al. (2002) simulation, 90 $\mu\text{g}/\text{day}$ was used for iodine intake. Baseline T3 and TSH are similar to the measured values. But, as was seen with fT4, the model fails to predict the observed changes in hormone levels in the adult subjects.

3.2.4 Téllez Téllez et al., (2005a), 2005b – Chilean epidemiological study in pregnant women

Téllez Téllez et al. (2005a, 2005b) reports the results of a longitudinal epidemiological study among pregnant women from three cities in Chile exposed to concentrations of perchlorate as high as 114 $\mu\text{g}/\text{L}$ in the public drinking water. The focus of the study was to evaluate maternal thyroid function during pregnancy, neonatal thyroid function and developmental status at birth, and breast milk iodine and perchlorate levels during lactation. The National Academy of Sciences (2005) has reviewed this study in the context of health implications for perchlorate ingestion and concluded this study should be considered in the evaluation of the US experience with perchlorate in drinking water. The total iodine nutrition among this cohort was also noted to be similar to that of US pregnant women (Téllez Téllez et al., 2005a); therefore, this study should be a key consideration in evaluating the relationship between perchlorate exposure, changes in fT4 in pregnant women and developmental status; however, it was not considered in Stage 2 of the USEPA (2017) assessment because it pre-dated the cutoff used by USEPA in their review (2010).

Results from this study indicated no effect on thyroid levels in early pregnancy, late pregnancy, or neonates at birth related to perchlorate in drinking water at concentrations up to 114 $\mu\text{g}/\text{L}$. Given these findings, this study provides a reasonable dataset for validating the impact of high perchlorate exposure concentrations in drinking water on potential changes in fT4 or TSH.

We also ran the (USEPA, 2017) BBDR model to simulate the Téllez Téllez et al. (2005a, 2005b) drinking water study (Table 3). The BBDR model predictions of fT4 for GW 13–16 are consistent with the negative results of the study, though the predicted concentrations are lower than those observed. This is not a strong validation of the model given the weak trend of changes in hormone levels seen in comparisons to other studies.

3.2.5. Summary: evaluation of model behavior

Our simulations of the Greer et al. (2002) and Braverman et al. (2006) studies with the BBDR model indicate that thyroid hormone levels are relatively insensitive to inhibition of thyroid iodine uptake by perchlorate exposures as high as 7 $\mu\text{g}/\text{kg}/\text{day}$. Moreover, our

Table 3
Simulation of the Téllez Téllez et al., (2005a), 2005b study of pregnant women exposed to perchlorate via drinking water.

Dose ($\mu\text{g}/\text{kg}/\text{d}$)	fT4 (pM)	
	Simulated	Measured
0.01	9.74	12.5
0.08	9.73	12.2
2	9.69	12.7

simulations of the Téllez Téllez et al. (2005a, 2005b) study with the BBDR model do not predict an effect on fT4 from exposures to perchlorate at up to 2 $\mu\text{g}/\text{kg}/\text{d}$, consistent with the fact that the exposures were demonstrated to be without effect to pregnant women in the study. However, the USEPA (2017) BBDR modeling analysis (Table 4, taken from USEPA 2017) predicted population-level changes in fT4 deficiency during the first trimester at perchlorate exposures nearly an order of magnitude lower (0.3 $\mu\text{g}/\text{kg}/\text{d}$). This discrepancy suggests that the metric used in the USEPA (2017) approach to assess population-level effects of perchlorate, i.e., a 1% or 5% increase the proportion of thyroxinemic mothers in early pregnancy assuming that all individuals have a low (75 $\mu\text{g}/\text{day}$) iodine intake and an inadequate TSH response (pTSH = 0.398 vs. 1), may be overly conservative.

3.3. Evaluation of the effect of model assumptions on predicted PODs

In order to assess the potential quantitative impact of some of the uncertainties in the BBDR model, we compared model predictions of percent change in fT4 and TSH for a range of perchlorate concentrations using two alternative parameterizations: (1) the parameterization used by the USEPA (2017) to generate their Tables 3, and (2) replacing the equation for HCGREG with the equation for VCHNG (in order to provide an appropriately coupled response to hCG stimulation of thyroidal iodine uptake and thyroid hormone production), and also setting pTSH = 1 (the nominal value, as opposed to the lower-bound value of 0.398 used by the USEPA). The simulations (Table 5) were performed with the model calibrated to either the median population thyroid hormone levels (using the script medset.r) or a low (thyroxinemic) population defined as fT4 < 10th percentile (using the script lowset.r). When predicting the effect of perchlorate exposure on fT4 for the median population there is not a significant difference between the USEPA results and the alternative parameterization; however, the USEPA model parameterization results in more than a factor of 2 greater sensitivity of TSH levels to perchlorate compared to the alternative parameterization. This difference is primarily due to the change in pTSH. On the other hand, when predicting the effect of perchlorate exposure on hypothyroxemic individuals, both fT4 and TSH responses to perchlorate exposure are significantly lower using the alternative parameterization. Thus, the parameters that were altered in the recent revision of the model (VCHNG, HCGreg, pTSH, KmNiS_p) increase the predicted effect on thyroid hormone levels compared to the expected response with the well-validated precursor event of iodide inhibition. The sensitivity of the prediction to changes in these parameters, and the disconnect between the prediction of iodide inhibition and thyroid hormone levels, calls for better justification – and evaluation – of the given parameter values.

3.4. Review of literature linking BBDR results to neurodevelopment outcomes

Chapter 5 of USEPA (2017) focuses on the SAB's recommendation to “Identify literature and conduct analyses to support the model outputs for the downstream steps” from the BBDR's predicted changes in thyroid hormones following exposure to perchlorate. Specifically, Chapter 5 was developed to present the process USEPA (2017) used to identify literature to support the draft approach for derivation of the MCLG for perchlorate. USEPA (2017) states, “Based on the recommendations of previous peer review panels, USEPA assumed that changes in thyroid hormone levels would be expected to lead to neurodevelopmental outcomes”, and because of this assumption, a complete systematic review of the body of literature on this topic was not performed. Instead, a “focused review of the published literature” was conducted.

The approach is inconsistent with recent recommendations from the National Research Council (NRC, 2014) regarding systematic review and evidence integration. These recommendations are currently being

Table 4

Summary of Results for the Amount of Perchlorate Needed to Increase the Proportion of Hypothyroxinemic, Low Iodine Individuals by a Defined Percentage (with hypothyroxinemia defined as $\text{fT4} < 10\text{th Percentile}$) (USEPA, 2017).

Gestational Week	fT4 (pmol/L) at the Hypothyroxinemic Cut Point (i.e. 10th Percentile of 170 $\mu\text{g/day}$ Iodine Intake Group) (Column 1)	Corresponding Percentile in 75 $\mu\text{g/day}$ Iodine Intake Group (Column 2) ^a	Perchlorate Dose ($\mu\text{g/kg/day}$) Associated with a 1 Percent Increase in Proportion Hypothyroxinemic (Column 3) ^a	Perchlorate Dose ($\mu\text{g/kg/day}$) Associated with a 5 Percent Increase in Proportion Hypothyroxinemic (Column 4) ^a
12	8.80	48.4	0.4	2.2
13	8.78	47.9	0.4	2.2
16	8.63	52.6	0.3	2.1

^a Results based on central effect estimates, pTSH in BBDR model set to 0.398.

incorporated into the USEPA's Integrated Risk Information System (IRIS) process and USEPA has recently released scoping and problem formulation materials for several new Integrated Risk Information System (IRIS) assessments, including ethylbenzene (USEPA, 2014a), and naphthalene (USEPA, 2014b). The approach applied in these assessments is intended to follow recommendations provided by the National Research Council (NRC, 2013). While development of MCLGs are not part of the IRIS process, the application of systematic review principles in the identification of studies to define the relationship between fT4 and neurodevelopmental effects, is needed. The application of these principles would not only assist in defining the highest quality studies to address a specific research question, they also provide a way to integrate all of the available evidence for the specific research questions raised by the SAB. Systematic reviews include the formulation of a specific question to be addressed and developing a protocol that specifies the methods that will be used to address the question. While a broad research question can lead to a large systematic review, if the research question is limited, such as in the case of perchlorate, then the systematic review becomes more focused.

For the USEPA (2017) draft MCLG approach, a systematic review question could have been easily developed based on the SAB recommendation (i.e. "Identify literature and conduct analyses to support the model outputs for the downstream steps") and the protocol would simply be focused on the methods for conducting the systematic review to address this very focused systematic review question in a transparent manner. Transparency being defined by USEPA as "sufficient information will be available to understand the scientific rationale behind decisions, as well as, reproduce methods used to identify and evaluate data". However, in the case of the literature identified for consideration in the draft MCLG approach for perchlorate, a well-defined protocol for all steps of the process has not been developed and therefore is inconsistent with the recommendations of the NRC (2013):

"A priori decisions and a predefined protocol are critical during the systematic review process (Berlin and Colditz, 1999; Dickersin, 2002); the protocol should describe the following steps: the research

question, the search strategy and data sources, the study inclusion and exclusion criteria, the data to be abstracted and derived from the original studies (such as sample size, exposure and outcome assessment methods, and confounders evaluated), the criteria and methods for pooling effect estimates and measures of variability among studies. Systematic reviews and meta-analyses need to be replicable; other investigators following the same steps should be able to identify the same articles, abstract the same data, and reach similar conclusions."

At each step of the process for identifying studies for use in the development of the MCLG approach for perchlorate, a detailed set of criteria is needed. For example, if decisions are made to include or exclude any studies, there should be very detailed criteria indicating why studies were included or excluded and it should be specified prior to the initiation of the literature searching process. The criteria for each step should be described in such a way that an independent reviewer could use it to replicate the results of the literature search and review; however, there are several areas in the USEPA (2017) draft MCLG approach for perchlorate where this level of detail is lacking, making it difficult for an independent reviewer to replicate the results.

3.4.1. Systematic review research questions

An overall hypothesis or systematic review research question should be developed that is based on the SAB recommendation to clarify the focus of the review and the linkage between altered maternal fT4 (as predicted by the BBDR model) and the potential for adverse neurodevelopmental effects in offspring. Some additional explanation as to how USEPA arrived at the specific neurodevelopmental outcomes of concern should be provided.

3.4.2. Searching the published literature

While the literature search key words are presented in the USEPA (2017) report, there is a lack of explanation as to the reasoning behind the focus on the outcome of concern. The research question should be used to develop the literature search. The major points used or

Table 5

Predicted fT4 and TSH Concentrations at Various Doses of Perchlorate for 75 $\mu\text{g/day}$ Iodine Intake.

Perchlorate Dose ($\mu\text{g/kg/day}$)	fT4 (pmol/L)			TSH (mIU/L) (% Change from 0 Dose)				
	(% Change from 0 Dose)							
	USEPA ^a	VCHNG + pTSH ^b	VCHNG + pTSH ^b	USEPA ^a	VCHNG + pTSH ^b	VCHNG + pTSH ^b		
	Population	Median	Median	Population	Median	Median	Low	
0	Absolute	8.6	9.9	7.5	2.2	1.5	3.0	
1	Percent Change	-0.74	-0.8	-0.31	3.3	1.4	1.9	
2		-1.5	-1.6	-0.61	6.6	2.7	3.8	
3		-2.1	-2.3	-0.9	10	4.1	5.7	
4		-2.8	-2.9	-1.2	14	5.5	5.7	
5		-3.4	-3.5	-1.5	17	6.9	7.7	
10		-6.2	-6.2	-2.8	36	14	19	

^a Results using pTSH = 0.398.

^b Results using HCGREG replaced with VCHNG, and pTSH = 1.

considered in developing the literature search strategy should be presented. In addition, there should be a detailed explanation of the criteria used to screen the literature search results. Furthermore, USEPA (2017) does not report the details of the literature search results. For each search string reported in Table 9 of the USEPA (2017) report, a total number of citations identified should be reported. In addition, the criteria used to screen the original search results should be clearly reported in the document. Essentially, each step of the literature search and review should be reported in such a way that any independent party could easily reproduce the results reported in Chapter 5 of USEPA (2017). The lack of this type of information does not allow the reader to determine if any key studies may have been removed from consideration.

3.4.3. Literature screening approach and selection of key studies

USEPA (2017) states that a 3 step approach was used to identify studies for consideration in the development of the approach for derivation of the MCLG for perchlorate. The approaches utilized by USEPA (2017) to identify the epidemiological studies for this evaluation were strictly focused on the appropriateness of the quantitative data for consideration in combination with the output of the BBDR model. Group 2 (studies with categorical analyses only) and Group 3 (studies with analyses not directly compatible with BBDR output) studies were apparently eliminated from consideration in the assessment. While not directly compatible with BBDR modeling output, it is possible that these studies may provide information important in understanding the potential relationship between changes in thyroid hormones and the potential for neurodevelopmental effects, as well as potential key confounders.

While 15 studies were identified in Group 1, only 5 of these were determined by USEPA to include analyses that could be used to connect the results of the BBDR model to incremental changes in adverse neurodevelopmental effects. A clearly defined set of inclusion and exclusion criteria should be provided to clearly convey to the reader why the other 40 studies in Groups 1, 2, and 3 were not considered. In addition, studies that provide no evidence of an inverse relationship between perchlorate exposure and serum thyroid function (e.g. Ghassabian et al., 2014; Modesto et al., 2015; Moleti et al., 2016; Noten et al., 2015) should also be considered to not only understand why these results are in contrast to the potential research question, but also that the overall weight of evidence can be determined. It is possible that the majority of studies provide evidence that critical factors that are not reported in some of the available studies may explain the reported changes in serum thyroid function.

3.4.4. Assessment of study quality and risk of bias

According to recent recommendations from the National Research Council (NRC, 2014), the National Toxicology Program's (NTP) Office of Health Assessment and Translation (OHAT) method for the assessment of study quality and risk of bias of the literature (NTP, 2015) is one method that should be considered for qualitative and quantitative assessments. "An assessment of study quality evaluates the extent to which the researchers conducted their research to the highest possible standards and how a study is reported. Risk of bias is related to the internal validity of a study and reflects study-design characteristics that can introduce a systematic error (or deviation from the true effect) that might affect the magnitude and even the direction of the apparent effect" (NRC, 2014). Each study meeting inclusion criteria in Group 1, 2, and 3, should be evaluated against a predetermined set of study quality and risk of bias criteria and the results of this evaluation should be presented in the perchlorate MCLG approach report.

3.4.5. Uncertainties critical to characterizing changes in thyroid hormone levels in pregnant women associated with neurodevelopmental changes in offspring

The draft MCLG approach presented in USEPA (2017) to predict

doses of perchlorate that would result in per unit changes in neurodevelopmental measures, is, as noted by USEPA (2017), "...dependent upon predictions from the BBDR model, the derivation of the distribution of fT4, and the evaluations of the relationship between fT4 and neurodevelopment. Each of these steps has inherent uncertainties associated with it."

A major source of uncertainty is related to the five studies in Group 1 with data that could be used to quantitatively describe the relationship between thyroid hormone levels in early pregnancy and changes in neurodevelopment (Pop et al., 1999, 2003; Pinken et al., 2013; Korevaar et al., 2016; Vermiglio et al., 2004). None of these five studies relied upon data from US populations or have been demonstrated to have iodine intake similar to US populations. Yet according to the American Thyroid Association (Alexander et al., 2017), the reference range of both TSH and fT4 in pregnant women varies depending upon ethnicity. While two studies in Group 1 focused on population groups within the United States, neither were considered for the model because T4 and not fT4 was measured in the pregnant females (Oken et al., 2009) and the relationship between fT4 and neurodevelopment was evaluated in late pregnancy and did not reach statistical significance (Chevrier et al., 2011). USEPA (2017) (Section 6.5.1) states "there is no reason to believe that the impact of fT4 on neurodevelopment would differ by country, unless there is a substantial difference in iodine intake". While USEPA (2017) does make an effort to evaluate changes in iodine intake in women from various populations, including the US, there are not substantial data reported in the peer-reviewed literature to validate the conclusions that the impact of fT4 on neurodevelopment would differ by population or uncertainty in iodine intake levels would have an impact on the derivation of the MCLG. This is inconsistent with data from the American Thyroid Association (Alexander et al., 2017) that suggest variability in the distribution of thyroid hormone levels across populations and even within ethnicities within a single population.

USEPA (2017) also notes that all five studies used for quantitative analysis relied on a one-time fT4 level during pregnancy (Section 6.5.5). The influence of changes in maternal fT4 on fetal brain development is likely greatest during early pregnancy. The variability in maternal fT4 levels during pregnancy and the lack of measurement of fT4 at time points throughout pregnancy in the studies provides a substantial data gap and lack of information needed to validate some of the assumptions relied upon in the development of the BBDR current model as well as the resulting predictions of the model. As stated in USEPA (2017),

"Circulating T3 and T4 levels in an individual are maintained within a narrow range by a negative feedback loop with TSH from the pituitary and TRH from the hypothalamus that operates around a "set-point." This set-point is different from individual to individual, which generates a population variance in blood levels of thyroid hormone that is considerably broader than the individual variance (Andersen et al., 2002). Therefore, in euthyroid individuals, serum T4 and T3 fluctuate within a fairly narrow range (about 10% of the population variance), maintained by the negative feedback relationship with serum TSH from the pituitary gland. This normal variation creates a situation where single measures of free or total T4 and TSH are a somewhat imprecise measure of an individual's average T4 and TSH concentrations (Andersen et al., 2002)."

Several other areas of uncertainty are also highlighted by USEPA (2017). Specifically, USEPA (2017) noted that none of the five studies carried forward provided iodine intake levels (Section 6.5.3), which adds significant uncertainty to the estimates. Three of the 5 studies (Pop et al., 1999, 2003; Vermiglio et al., 2004) also have populations of less than 30 decreasing the statistical power of the studies (section 6.5.4) relied upon for establishing the relationship between changes in fT4 and neurodevelopmental changes. USEPA (2017) also noted uncertainties in regard to the analytical methods used to evaluate fT4

levels and while approaches are being introduced to standardize analytical methods, results at different time points and from different countries may vary considerably due to differences in analytical procedures (USEPA, 2017). USEPA (2017) also notes that “there is uncertainty regarding the true fT4 levels at various percentiles in the distribution around the median output from the BBDR model. This is exemplified by the fact that in this analysis larger unit changes are being seen with increasing percentiles of fT4 in most analyses.” Finally, other confounders such as iron deficiency were not considered in the analysis. Iron deficiency in pregnant mothers, which is noted in approximately 18% of pregnant women in the US (Cantor et al., 2015), may also be associated with hypothyroxinemia (Yu et al., 2015) and failing to directly account for a relationship between iron deficiency and hypothyroxinemia may introduce an uncertainty into this analysis.

While all these uncertainties are noted by USEPA (2017), there is no attempt to adjust the draft MCLG approach in any way to account for these uncertainties. Many of these, especially confounders such as iron deficiency in the study population and a lack of information on iodide intake, can have a significant effect in characterizing changes in thyroid hormone levels associated with changes in neurodevelopmental outcomes. In the absence of adequately accounting for these uncertainties, it is difficult to have confidence that BBDR model predictions of small changes in a specific thyroid hormone (e.g. fT4) may accurately predict the potential for neurodevelopmental effects.

The inadequacy of the USEPA (2017) literature review is substantiated by the comments of the External Peer Review for USEPA's Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water (Versar, 2018). Comments regarding the USEPA (2017) literature search included:

- “The literature search produced ten studies (that assessed maternal serum FT4 concentrations as a continuous measure which did not observe an adverse effect on offspring neurocognition), as well as those in Group 2 that assessed serum FT4 as categorical measures. Although their inclusion may not necessarily be recommended in the final model, comparison of the estimated effects on the various neurocognitive outcomes with and without these may indeed inform the degree of uncertainty inherent in the present model. Several of the studies in Group 2 were able to demonstrate significant adverse outcomes (Berbel et al., 2009 as one excellent example), and also their more global nature would help support the generalizability of the present model.”
- “Excluding these studies lessens the power of the total sample size and thus the ability to detect an association between maternal hypothyroxinemia and any of the offspring outcomes, but provides what may be a somewhat exaggerated estimate of the potential adverse effects of perchlorate exposure. This approach is more conservative, to which there are pros and cons of doing so, toward derivation of a perchlorate MCLG. With this approach, the goal is to minimize exposure to the lowest perchlorate concentration associated with any number of adverse outcomes. I would favor the more liberal public health approach, which is inclusion of all available studies, whether they are positive or negative. Although the perchlorate MCLG may be higher, this latter approach would be consistent with using all available evidence to improve the scientific rigor of the proposed study question.”

The peer reviewers also suggested a number of additional peer-reviewed studies that they felt should have been considered to inform BBDR modeling of the quantitative relationship between thyroid hormone levels and neurodevelopmental outcomes:

- Báñez-López S, Jesus-Obregon M, Bernal J, Guadaño-Ferraz A. 2017. Thyroid Hormone Economy in the Perinatal Mouse Brain: Implications for Cerebral Cortex Development. *Cerebral Cortex*, 28(5): 1783–1793.

- Bath S, Steer C, Golding J, Emmett P, Raymen M. 2013. Effect of inadequate iodine status in UK pregnant women on cognitive outcomes in their children: results from the Avon Longitudinal Study of Parents and Children (ALSPAC). *The Lancet*, 382(9889): 331–337.
- Bernal J. 2017. Thyroid hormone regulated genes in cerebral cortex development. *Journal of Endocrinology*, 232(2): R83–R97.
- Casey B, Thom E. 2017. Subclinical Hypothyroidism or Hypothyroxinemia in Pregnancy. *The New England Journal of Medicine*, 377(7): 701.
- Casey B, Thom E, Peacemann A, Varner M, Sorokin Y, Hirtz D, Reddy U, Wapner R, Thorp J, Saade G, Tita A, Rouse D, Sibai B, Iams J, Mercer B, Tolosa J, Caritis S, VanDorsten JP. 2017. Treatment of Subclinical Hypothyroidism or Hypothyroxinemia in Pregnancy. *The New England Journal of Medicine*, 376: 815–825.
- Endendijk J, Wijnen H, Pop V, van Baar A. 2017. Maternal thyroid hormone trajectories during pregnancy and child behavioral problems. *Hormones and Behavior*, 94: 84–92.
- Hales C, Taylor P, Channon S, Paradise R, McEwan K, Zhang L, Gyedu M, Bakhsh O, Muller I, Draman M, Gregory J, Dayan J, Rees D, Ludgate M. 2018. Controlled Antenatal Thyroid Screening II: effect of treating maternal sub-optimal thyroid function on childhood cognition. *The Journal of Clinical Endocrinology and Metabolism*, 103(4): 1583–1591.
- Lazarus J, Bestwick J, Channon S, Paradise R, Maina A, Rees R, Chiusano E, John R, Guaraldo V, George L, Perona M, Dall'Amico D, Parkes A, Joomun M, Wald NJ. 2012. Antenatal Thyroid Screening and Childhood Cognitive Function. *The New England Journal of Medicine*, 366: 493–501.
- Taylor PN, Okosieme OE, Murphy R, Hales C, Chiusano E, Maina A, Joomun M, Bestwick JP, Smyth P, Paradise R, Channon S, Braverman LE, Dayan CM, Lazarus JH, Pearce EN. 2014. Maternal Perchlorate Levels in Women with Borderline Thyroid Function During Pregnancy and the Cognitive Development of Their Offspring: Data from the Controlled Antenatal Thyroid Study. *The Journal of Clinical Endocrinology & Metabolism*, 99(11): 4291–4298.

In the draft MCLG approach, USEPA (2017) focused on five studies that evaluated the relationship of maternal fT4 and several neurodevelopmental endpoints (IQ, mental development index (MDI), psychomotor development index (PDI), standard deviation of reaction time), based on measurements of fT4 during early pregnancy. Results from previous studies have provided the basis for No Observed Effect Levels (NOELs) for health effects of perchlorate in the development of Reference Doses and currently recommended Health Reference Levels (HRLs), including Greer et al. (2002) in which adult men and women were exposed to perchlorate in drinking water at doses of 0.007, 0.02, 0.1, or 0.5 mg/kg/day for 14 days demonstrated a NOEL for perchlorate inhibition of radioiodide uptake by the thyroid NIS following exposure to 7 µg/kg/day. The point of departure from the Greer et al. (2002) study represents a perchlorate level that precedes the inhibition of iodine uptake by the thyroid. The NAS RfD developed based on the point of departure (POD) from this study is a deviation from the Agency's traditional approach of using a No Observed Adverse Effect Level (NOAEL) for regulatory actions. The NAS's use of a No Observed Effect Level (NOEL) is based on “using a nonadverse effect that is upstream of the adverse effect [which] is a more conservative and health protective approach”.

While these studies have not been conducted in pregnant women (the population of interest for the draft MCLG approach), as noted by USEPA (2017):

“...the BBDR model predicts very little difference in non-pregnant and first-trimester response to perchlorate. This likely occurs because the half-life of (organified) iodine in the adult thyroid is around six months, hence the availability of thyroidal iodine in the

first trimester pregnant woman is determined to a very large extent by her nutrition and perchlorate exposure several years preceding pregnancy.”

This suggests that a comparison of the current modeling results to those from studies conducted in adults should provide insight into the predictions of the model and the conclusions regarding the changes in thyroid hormone levels that may result in neurodevelopmental effects.

The current draft approach for deriving the MCLG assumes any exposure to perchlorate reduces fT4 to some extent (p. 3–17 of USEPA, 2017). In addition, linear regression analyses conducted to evaluate the relationship between changes in fT4 and neurodevelopmental effects further assumes any change in fT4 results in some risk of neurodevelopmental effects. These assumptions are in contrast to the results from Greer et al. (2002) in which exposures to perchlorate were as high as 500 µg/kg/day and no impact on thyroid hormone levels was observed. This was true for both men and women. In addition, in a study conducted by Braverman et al. (2006), 6 months of exposure to perchlorate in capsules at doses up to 3 mg/day (approximately 40 µg/kg/day) was reported to have no effect on thyroid function, including inhibition of thyroid iodide uptake as well as serum levels of thyroid hormones, TSH, and Tg in a small group of volunteers.

USEPA (2017) notes (p. 6–16) that from results of the literature review, it appears the relationship between maternal fT4 and fetal brain development has a temporal relationship, with this influence likely being greatest in early pregnancy (i.e. prior to mid-gestation). The focus of the evaluation is on gestational weeks 12, 13, and 16, where the mother's fT4 levels will have the greatest impact on the fetus. This should allow for comparison to the model results in pregnant women to results from previous studies focused on identification of perchlorate concentrations that would impact fT4 levels in adult women, such as the Greer et al. (2002) study.

Based on the BBDR model predictions, USEPA (2017) estimates that a perchlorate dose of 0.3–0.4 µg/kg/day would result in a 1% increase in the proportion of the population with hypothyroxinemia and a perchlorate dose of 2.1–2.2 µg/kg/day would result in a 5% increase in proportion of the population with hypothyroxinemia. These modeling results suggest a potential for a significant change in thyroid hormones, as well as adverse effects on neurodevelopment at doses of perchlorate exposure for which there is evidence that decreases in fT4 are not observed. Based on the mode of action proposed by USEPA (2017), decreases in fT4 and increases in TSH would be prerequisite steps for the potential for neurodevelopmental effects. These changes in hormone levels are not observed in the Greer et al. (2002) study following exposure up to 500 µg/kg/day. The draft MCLG approach suggests population changes in fT4 would be observed that would shift the proportion of pregnant women that would be hypothyroxinemic at doses of perchlorate below the previously defined NOEL (7 µg/kg/day).

Table 6 (Table 39 of USEPA, 2017) provides the predicted dose of perchlorate per unit change in neurodevelopmental measure for low iodine intake individuals. Those for IQ are approximately at or above (6.5–45 µg/kg/day) the NOEL from Greer et al. (2002) and are associated with decreases in fT4 of 4.3–18.7%. The doses associated with other neurodevelopmental endpoints are 1.7–3.0 µg/kg/day and are associated with decreases in fT4 of 1.3–2.4%. These percent changes in fT4 are very small and considering the potential uncertainty and variability in measuring fT4 levels, there is a lack of evidence that such small changes in fT4 will result in clinical observations. Reference ranges for fT4 are 0.9–2.5 ng/dL in infants (0–5 days) and 0.9–1.7 ng/dL in adults (> 20 yrs) (<https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/8725>). Thus, for an adult, at the low end of the reference range, we would expect a change from 0.900 to 0.878 ng/dL, a value that given the number of significant figures in the reference value would not be measurable. The dose of perchlorate estimated to result in a 1% or 5% increase in the proportion of hypothyroxinemic pregnant women is even lower, ranging from 0.3

to 2.2 µg/kg/day. USEPA (2017) findings are contrary to multiple studies in adults and pregnant women (Greer et al., 2002; Braverman et al., 2006; Téllez Téllez et al., 2005a, 2005b) provide robust evidence that no impact on iodine uptake or thyroid hormone levels would be expected at these dose levels. Based on the mode of action proposed by USEPA (2017), these precursor impacts are necessary to generate the neurodevelopmental effects derived from the BBDR model.

4. Discussion

A critical review of the (USEPA) 2017 report entitled “Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water”, as well as the BBDR model that was proposed for use in derivation of the MCLG, was conducted. Overall, conducting this review and assessment of the BBDR model was beset by multiple challenges and the effort highlighted a number of uncertainties in the use of the model. The main challenges that the review presented were due to the complexity of the BBDR model itself. The co-authors of this review, who are widely considered to be experts in the area of PBPK and BBDR model development, found it difficult to evaluate the complex interactions of model parameters and their relationship to the predictions of the model. In our efforts to reproduce simulations provided in USEPA (2017), it was noted that instructions for running the model for different scenarios, and documentation of the rationale for the model parameter values associated with them, were sometimes inadequate; this deficiency, which is inevitable in a complex model, was exacerbated by the number of code scripts required to set the parameters used to generate the various results in the document. As a result, the ability to independently verify all aspects of the model were impeded by uncertainties associated with the steps necessary to reproduce figures and tables in the report, or to perform comparisons of model predictions to data for alternative exposure scenarios or studies.

As suggested by C.A.R. Hoare in his 1980 ACM Turing Award Lecture: “There are two ways of constructing a software design: One way is to make it so simple that there are obviously no deficiencies and the other way is to make it so complicated that there are no obvious deficiencies.” By their nature, BBDR models are seldom simple; to the extent that BBDR models attempt to describe complex biological systems they will inherently be difficult to comprehend. The criticisms of the perchlorate PBPK model in this case study are not meant to suggest that the model is incorrect or un-useful, and they should not be taken as criticisms of the utility of BBDR modeling in general. Used appropriately, BBDR models can provide important information for better risk assessment decision-making. The issue that needs to be addressed in each case is whether a BBDR model is fit for the intended purpose of using it in the risk assessment.

The first use of PBPK modeling in risk assessments dates back to the 1980s (USEPA, 1987) and yet the application of PBPK modeling to replace default dosimetry remains controversial, primarily due to concerns regarding model uncertainty. To address these concerns, the OMB (2007) memorandum on risk analysis recommended the presentation of results from multiple dose-response approaches to provide a more robust risk characterization. In this scenario, a fit-for-purpose BBDR model can provide information on the most scientifically plausible risk estimate for comparison with the results of default approaches (Clewell et al., 2008). Consistent with this OMB recommendation, one focus of our evaluation was determining how the results of the BBDR modeling could inform the likelihood that the current perchlorate guideline (USEPA, 2005), which is based on inhibition of thyroidal iodine uptake in adults, is also protective of concerns regarding neurodevelopmental effects of perchlorate. This question is discussed in the Conclusion.

The current BBDR model that was relied upon for the USEPA (2017) draft approach is an extension of previous models that have been validated and published in the peer-reviewed literature (Clewell et al., 2007; Merrill et al., 2003; Lumen et al., 2013). Similar values for key

Table 6

Predicted Dose of Perchlorate per Unit Change in Neurodevelopmental Measure for Low Iodine Intake Individuals based on Central Effect Estimates at the Median fT4 level (USEPA, 2017).

Study	Endpoint	Δ fT4 in pmol/L (% Δ fT4 from 0 dose perchlorate, iodine intake = 75 μ g/day)	Dose of perchlorate per unit change in endpoint (μ g/kg/day) ^a
Korevaar et al. (2016) Quadratic	IQ	–1.08 (12.2%)	23
Korevaar et al. (2016) USEPA Independent Analysis: Bivariate	IQ	–0.98 (11.1%)	20
Korevaar et al. (2016) USEPA Independent Analysis: Multivariate	IQ	–1.66 (18.7%)	45
Vermiglio et al. (2004)	IQ	–0.37 (4.3%)	6.5
Pep et al. (2003)	MDI	–0.15 (1.7%)	2.2
Pep et al. (2003)	PDI	–0.12 (1.3%)	1.7
Pep et al. (1999)	PDI	–0.12 (1.3%)	1.7
Finken et al. (2013)	SD of Reaction Time	–0.21 (2.4%)	3.0
BBDR model (USEPA, 2017)	1% or 5% increase in proportion of hypothyroxinemic pregnant women ^b	1% or 5%	0.3–0.4 ^c [1%] 2.1–2.2 ^c [5%]

^a Based on the regression analysis for the range of fT4 data within each study. Central beta estimates of the low iodide intake population (= 75 μ g/day) are presented.

^b Hypothyroxinemia defined as fT4 < 10th percentile.

^c Range based on gestational week used to perform the analysis (12–16 weeks).

parameters have been successfully used across the previous models, yet changes were made in the current model or new parameters added (e.g. VCHNG, HCGreg, pTSH, KmNiS), often with little or no evidence or justification provided to support these revisions in the USEPA (2017) documentation. Additional support for these changes will be needed to provide validation of the current revisions to the BBDR model and to provide confidence in the predictions of changes in fT4 made by the model.

Certainly, confidence in the BBDR model predictions is undermined by the model's inability to simulate the results from the Steinmaus et al. (2016) study. In Appendix B of USEPA (2017), a comparison of the predicted changes in both fT4 and TSH from the BBDR model were compared to the results reported by Steinmaus et al. (2016) (reproduced in Fig. 6). The Steinmaus et al. (2016) study was conducted to evaluate the potential for perchlorate exposure to impact thyroid hormone levels in pregnant women in San Diego. This comparison clearly highlights the differences between the model predictions and those from a published study. The baseline BBDR simulations with normal iodine intake (170 μ g/day) demonstrate no change in fT4, which is consistent with other studies in which no impact on fT4 has been observed at doses up to 7 μ g/kg/day (Greer et al., 2002; Braverman et al., 2006). The BBDR model underpredicted changes in fT4, even in the scenario with low dietary iodine intake (75 μ g/day), when compared to the changes reported by Steinmaus et al. (2016). This discrepancy calls into question the ability of the model to predict changes in fT4 associated with perchlorate exposure. In particular, the proposed MCLG approach depends on model predictions of small changes in fT4 as low as approximately 1% (Table 6) being associated with unit changes in neurodevelopmental endpoints. Predictions of this precision would require a level of model precision that has not been demonstrated by comparisons to existing data.

Many of the changes in fT4 that are predicted by the draft MCLG approach to estimate impact on the population distribution of fT4 and therefore result in per unit changes in neurodevelopmental outcomes are small percent changes (some as low as a 1.3–4.3% change). This would appear to suggest that the extended version of the BBDR model has a capability to estimate small changes in fT4 with a level of precision that is not demonstrated by any adequate validation. In fact, BBDR model predictions of fT4 underpredict observed data in human studies (Tables 1 and 3) by as much as 25–35%. Moreover, considering the variability of fT4 in the populations of interest, there is uncertainty as to whether these slight changes could be measured clinically,

considering the greater impact of iodine intake on hormone levels. Considering the lack of data to support critical parameters and assumptions in the model, as well as the impact of the variability of iodine intake on model predictions, it seems crucial that validation of the BBDR model by comparison with observed data be used to provide confidence in the predictions of the BBDR model. However, the BBDR model clearly fails the only comparison that has been conducted (Fig. 6), with the BBDR model predictions falling outside the bounds of the statistical confidence limits estimated for the Steinmaus et al. (2016) relationship between perchlorate dose and fT4. Each of the components of the BBDR model combined result in compounded uncertainty in the modeling results.

Until additional data are available to validate current extensions of the BBDR model to the pregnant woman, the Greer et al. (2002) and Braverman et al. (2006) studies provide the critical information in determining concentrations of perchlorate that do not result in significant inhibition of iodide uptake and, therefore, impacts on fT4. Based on recommendations from the National Academy of Sciences (2005), points of departure provided by these studies used in combination with uncertainty factors were considered to be protective of sensitive subpopulations, this approach has previously been relied upon to support guidelines for perchlorate in drinking water under the Safe Drinking Water Act (USEPA, 2008), and has also been used more recently by JECFA (2011) and EFSA (2014) in their regulation of perchlorate.

5. Conclusions

We applaud the USEPA for the application of a BBDR model in their draft MCLG approaches, as these models integrate the available science for a compound of interest. However, while the hormone component of the model is a scientific improvement in terms of incorporating the available biology, there is a lack of data to provide critical validation in multiple steps of the proposed approach and to support several assumptions/parameters within the BBDR model. In particular, while no major structural defects in the USEPA (2017) BBDR model were identified, there are a number of uncertainties in the model parameterization that call into question its use for predicting very small changes in clinical hormone values, such as a 1% change in fT4 (Tables 4–6). While the model prediction for 1% change in fT4 (0.3–0.4 μ g/kg/day) would yield a POD lower than the USEPA (2005) RfD, that level of precision is a not supported by the comparison of the model predictions with

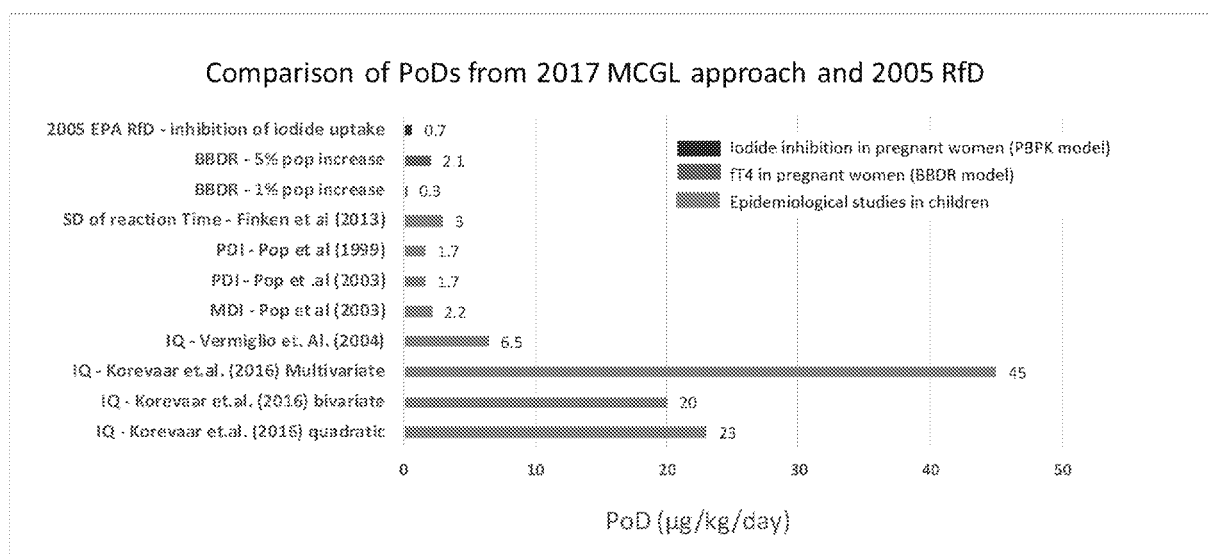


Fig. 7. Comparison of PoDs calculated using the USEPA (2017) BBDR model-based PoDs (blue and green bars) with the USEPA (2005) RfD (red bar). (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

available data. Nonetheless, the consistency of the model-predicted PODs based on the epidemiological endpoints (Table 6), and the relationship of these results with previous risk assessments based on biologically sound precursors (iodide inhibition in thyroid), indicate that the interim health standard would be sufficiently protective against the developmental neurological endpoints of concern, as illustrated in Fig. 7, which compares the point of departure from the USEPA (2005) IRIS assessment with the PoDs calculated by the BBDR model in the USEPA (2017) report (Table 6). The USEPA (2005) RfD (red bar) is protective for all of the endpoints from epidemiological studies and is consistent with a change in population fT4 levels of less than 5%.

Beginning with the initial risk characterization for perchlorate (USEPA, 2002), the fundamental underpinning of the agency's risk assessment approach has been the use of an obligatory precursor as a conservative basis for protecting against downstream health effects. As elaborated in the original documentation (USEPA, 2003), the effects of perchlorate are mediated by the inhibition of thyroidal iodine uptake by perchlorate. Unless perchlorate concentrations in the blood are sufficient to disrupt iodine uptake, there is no plausible basis for suggesting an effect of perchlorate on thyroid hormone homeostasis or subsequent events leading to developmental or (in the rat) carcinogenic effects. The recent studies suggesting a relationship between perchlorate exposure and decreased fT4 do not impeach this causal relationship. Therefore, until the significant uncertainties in the current BBDR model and draft MCLG approaches can be addressed, USEPA should continue to rely on the RfD approach based on inhibition of thyroidal iodine uptake (USEPA (2005), as recommended by the National Academy of Sciences (2005) for any further regulatory action. The USEPA (2005) RfD includes an intraspecies uncertainty factor of 10 “to protect the most sensitive population, the fetuses of pregnant women who might have hypothyroidism or iodide deficiency.” None of the predictions of the BBDR model suggest that this uncertainty factor is inadequate.

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Appointment

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 3/11/2019 5:12:10 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Thomas, Amanda L. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Glass, Jacob S. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Theroux, Rich P. EOP/OMB [Ex. 6 Personal Privacy (PP)]

Subject: Perchlorate

Location: Dial-in: [Ex. 6 Personal Privacy (PP)] Passcode: [Ex. 6 Personal Privacy (PP)]

Start: 3/11/2019 8:00:00 PM

End: 3/11/2019 8:30:00 PM

Show Time As: Tentative

Recurrence: (none)

Appointment

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/17/2019 8:50:11 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]

Subject: Accepted: Hold for OMB call re Perchlorate
Location: EPA East 2331 A or [Ex. 6 Personal Privacy (PP)] code: [Ex. 6 Personal Privacy (PP)]

Start: 5/21/2019 7:30:00 PM
End: 5/21/2019 8:30:00 PM
Show Time As: Busy

Recurrence: (none)

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 3/11/2019 5:10:59 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Nickerson, William [Nickerson.William@epa.gov]
Subject: RE: Perchlorate

Excellent and thanks. Will send you an invitation for 4:00.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Monday, March 11, 2019 12:49 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: Perchlorate

Vlad I am available after 3:30.

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]>
Sent: Monday, March 11, 2019 12:20 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: Perchlorate

Eric -

Any chance you're available for another call on perchlorate later today or tomorrow morning? We've read the Lead NAAQS and have some more questions on how you're proposing to rely on IQ in general and the 1 or 2 IQ point decrement in particular.

Vlad

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/17/2019 7:19:32 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]
Subject: RE: Hold for OMB call re Perchlorate

That would be perfect. However, could you clarify purpose of this call though? Do you expect to have already reviewed OMB's comments sent the previous night and have responses ready? If so and in the interest of efficiency, want to check on availability of Margo and April too.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Friday, May 17, 2019 2:52 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Christ, Lisa <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>; Khera, Rajiv <Khera.Rajiv@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: Hold for OMB call re Perchlorate

Would 3:00 pm work better?

From: Dorjets, Vlad EOP/OMB [mailto:Ex. 6 Personal Privacy (PP)]
Sent: Friday, May 17, 2019 2:19 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>; Khera, Rajiv <Khera.Rajiv@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: Hold for OMB call re Perchlorate

I am supposed to have a call with some of your colleagues in OWOW at this time but can try to reschedule it if this is the only time that works for you.

-----Original Appointment-----

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Friday, May 17, 2019 12:15 PM
To: Christ, Lisa; Hernandez-Quinones, Samuel; Khera, Rajiv; Nickerson, William; Dorjets, Vlad EOP/OMB
Subject: Hold for OMB call re Perchlorate
When: Tuesday, May 21, 2019 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: EPA East 2331 A or [Ex. 6 Personal Privacy (PP)] code: [Ex. 6 Personal Privacy (PP)]

Due to some schedule changes I was just informed of regarding signature of this proposal we will need to have our discussion on Tuesday rather than Wednesday. Can we please hold this time for a follow up discussion?

Appointment

From: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]

Sent: 3/8/2019 1:33:33 AM

To: Burneson, Eric [Burneson.Eric@epa.gov]

Subject: Accepted: Perchlorate Proposed NPDWR

Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)] Conf ID [Ex. 6 Personal Privacy (PP)]

Start: 3/7/2019 9:00:00 PM

End: 3/7/2019 10:00:00 PM

Recurrence: (none)

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/1/2019 12:16:21 AM
To: Nickerson, William [Nickerson.William@epa.gov]
CC: Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Interagency Comments on Draft Perchlorate MCL NPRM (2 of 2)
Attachments: EPA Perchlorate MCL NPRM (DOD).pdf; EPA Perchlorate MCL TSD (CDC).docx; EPA Perchlorate MCL TSD (DOD).pdf; EPA Perchlorate MCL (NASA).docx; EPA Perchlorate MCL (SBA).docx; EPA Perchlorate MCL HRRCA (CDC).docx; EPA Perchlorate MCL HRRCA (DOD).pdf; EPA Perchlorate MCL NPRM (CDC FDA NIH).docx

Bill,

Per my previous message, please find attached comments from certain interagency reviewers on EPA's draft proposal setting an MCL for perchlorate.

Vlad



February 9, 2018

Jonathan M. Samet, MD, MS (Chair)
Committee to Review of Advances Made to the IRIS Process
Board on Environmental Studies and Toxicology, Division of Earth and Life Studies
The National Academies of Science, Engineering, and Medicine
2101 Constitution Avenue Northwest
Washington, DC 20418

RE: Comments on Review of Advances Made to the IRIS Process: A Workshop (PIN: DELS-BEST-17-03)

Dear Dr. Samet:

I am writing to make several specific recommendations regarding the Integrated Risk Inventory System (IRIS) that would benefit EPA and the scientific community. My office has been working on issues related to the IRIS since 2011. Small businesses are very concerned with the accuracy of scientific determinations made under IRIS since these assessments are often used in regulations promulgated by the agency and other regulatory bodies. Advocacy has several observations and recommendations for your consideration in your workshop critique of EPA's post-2011 efforts to improve IRIS.

Office of Advocacy

Congress established the Office of Advocacy under Pub. L. No. 94-305 to advocate the views of small entities before Federal agencies and Congress. As Advocacy is an independent body within the U.S. Small Business Administration (SBA), the views expressed by Advocacy do not necessarily reflect either the position of the Administration or the SBA.

Background

Advocacy observed in late 2010 and early 2011, that EPA was having great difficulty addressing scientific issues for a variety of chemicals, including arsenic, formaldehyde, hexavalent chromium and perchlorate. Advocacy invited attorneys and scientists to present these issues before a small business environmental roundtable discussion in May 2011. There was a clear pattern – EPA scientific analyses were inadequately justified and lacked transparency, often resulting in a finding of additional risk that may not be justified under a more robust examination.

Coincidentally, the Formaldehyde NRC report was released in April 2011, which found that EPA was having similar difficulties in the IRIS program. The NRC sharply critiqued the IRIS program for persistent failures to provide objective scientific evidence to support its conclusions.¹ The NRC noted problems with the objectivity, scientific accuracy and transparency needed to ensure high quality assessments. Advocacy believes that more transparent and stronger science could emerge at IRIS. Such a development could serve as a template for improvements at EPA and possibly other national and international bodies that perform scientific assessments. Advocacy has worked closely with EPA since 2011 on IRIS implementation, and endorsed the excellent IRIS enhancements announced in July 2013 by Ken Olden, the previous Director of the National Center for Environmental Assessment (NCEA).² Advocacy commends EPA's accomplishments in implementing those revised procedures to date (hereinafter "IRIS 2.0").

Discussion and Recommendations

As a close observer and participant in several IRIS-related proceedings over many years, Advocacy believes that EPA has made great progress in implementing IRIS 2.0. In particular, as demonstrated at this recent NRC workshop,³ EPA has created a world class system to perform systematic review for chemical hazard assessments, including identification of study quality and criteria for selecting key studies for quantitative analysis, as demonstrated by the discussion at the workshop, the draft systematic review protocols,⁴ and at the presentations in the poster session. Advocacy applauds EPA's substantial achievements over this short period of time. However, EPA has not yet demonstrated the scientific maturity and expertise to implement the final critical steps in the assessment addressed by the NRC recommendations, specifically the judgments needed to evaluate study quality, select key studies, utilize expert judgment evaluating complex streams of evidence, and finally to derive sound toxicity values. EPA did reveal an understanding of the final steps needed to complete the assessment, but it hasn't demonstrated that these steps can be successfully implemented. Unfortunately, EPA did not provide any mature assessments under IRIS 2.0 to allow the NRC to do a review on this final key portion of the IRIS improvements. Advocacy recommends that NRC prioritize review of the EPA IRIS handbook and IRIS 2.0 assessments, the key documents that would show how close EPA is to implementing the final elements of the IRIS recommendations.

Advocacy believes that the most recent evidence regarding the EPA ability to implement these final scientific judgments is unsettling. Public statements at the workshop by Dr. Sam Cohen, of the University of Nebraska Medical Center and Dr. Jessica Ryman-Rasmussen of API regarding

¹ Review of EPA Formaldehyde Committee to Review EPA's Draft IRIS Assessment of Formaldehyde. National Academy of Sciences, April 8, 2011, Washington, D.C..

² [https://yosemite.epa.gov/sab/sabproduct.nsf/86F8A25AE5BBB2ED85257D0F0057DE17/\\$File/PDF+of+VJCogliano-SABjuly2014+\[Compatibility+Mode\].pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/86F8A25AE5BBB2ED85257D0F0057DE17/$File/PDF+of+VJCogliano-SABjuly2014+[Compatibility+Mode].pdf)

³ Review of Advances Made to the IRIS Process: A Workshop (PIN: DELS-BEST-17-03), February 1-2, 2018.

⁴ The uranium and chloroform protocols were made available to the NRC, and public comments on these protocols are due to EPA by March 2. <https://www.federalregister.gov/documents/2018/01/31/2018-01915/availability-of-the-integrated-risk-information-system-iris-assessment-plan-for-uranium>; <https://www.federalregister.gov/documents/2018/01/31/2018-01914/availability-of-the-systematic-review-protocol-for-the-chloroform-integrated-risk-information-system>

TBA (tert butyl alcohol) and ETBE (ethyl tertiary butyl ether) indicate that, despite the lengthy and comprehensive discussion in the previous June 2016 Public Science meeting addressing the key science issues, EPA failed to account for the pathology-related criticisms that EPA was improperly using rat kidney tumor data to represent noncancer risk to humans. The subsequent September 2017 peer review discussion highlighted again the lack of pathology expertise available to EPA, which contributed to this confusion.⁵ One of the peer reviewers, Dr. Lorenz Rhomberg, a toxicologist from the consulting firm, Gradient, stated that at a minimum, EPA needed to acknowledge “a significant dissenting body of expert opinion.”⁶

Tina Bahadori, the current Director of NCEA, did explain after the API testimony at the workshop, that EPA judged that it was too late to incorporate IRIS 2.0 procedures into the TBA and ETBE assessments. However, the Agency could have brought EPA or non-EPA pathologists to engage the peer reviewers in the September 2017 peer review to at least partially remedy the known shortcomings of the assessment. There was substantial public input from the earlier June 2016 public session which made the various inadequacies quite apparent to anyone in attendance, but the new draft 2017 assessments failed to correct the errors. EPA needs to redouble its efforts at IRIS step one public meetings to discuss the key issues and, most importantly, to take these concerns more seriously.⁷ In addition, EPA proposed a derivation of a toxicity value for ETBE, despite the EPA protocol that such values should not be derived for chemicals with only “suggested evidence of carcinogenicity.”⁸ This workshop testimony on TBA and ETBE was reminiscent of the problems observed in the 2011 NRC report. Our most recent experience with the perchlorate review by the EPA Office of Water last month is instructive. Even with the help of EPA IRIS program, EPA failed to perform any quality review of the five key studies selected for quantitative analysis. The agency selected only the five positive studies for quantitative analysis, and did not use the negative studies.⁹ EPA

⁵ See details in the Cohen and Ryman-Rasmussen comments.

⁶ Dr. Rhomberg wrote in his September 2017 preliminary peer review comments:

In public comments, some strong views, supported by analysis of a specifically convened PWG, are expressed regarding whether the kidney endpoints are separable, whether they are better considered as various aspects of Chronic Progressive Nephropathy (CPN), and whether they are relevant to processes that could occur in humans. Importantly, the endpoint chosen as critical, urothelial hyperplasia, is characterized by the PWG as a stage in CPN. In sum, the question of the validity and applicability of the endpoints analyzed for the oral RfD needs to be carefully examined. Even if the decision is to use them, that use must be couched in prominent caveats that acknowledges a significant dissenting body of expert opinion.

Even if one decides to employ these endpoints, it has been said by knowledgeable public commenters that, because the endpoints are seen as a suite of CPN manifestations, not all appearances will necessarily be noted in pathological examination, and the counts (and denominators) may be inappropriate. This question needs a clear resolution if the data are to be taken as valid for analysis.

⁷ Under the 2013 IRIS Enhancements, EPA holds a “step one” public meeting to discuss literature search, evidence tables, exposure-response figures, and key issues. In our experience, these public meetings of experts in the field, including scientists selected by the NRC, have been of invaluable assistance in bringing significant new information to EPA. It remains to be determined how well EPA will address the new information.

⁸ EPA Guidelines for Carcinogenic Risk Assessment, March 2005, p. 3-2; Ryman-Rasmussen Comments, January 26, 2018, pp. 4-5.

⁹ NASA Comments, November 20, 2017, p. 4.

explicitly declined to perform a systematic review of the literature in the structured manner now adopted in IRIS.¹⁰ Although this activity was not intended to meet IRIS 2.0 standards, EPA's effort in 2017, six years after the NRC report, appeared to fall far short of these standards. A study that would inform the setting of a drinking water standard for the U.S. population warrants more expert judgment and precision.

Recommendations

Advocacy has some specific recommendations to the NRC for a more robust review that would benefit EPA and the scientific community. The Office urges the NRC to take five steps:

1. Review the material provided to date by EPA, which include the systematic review protocols and the workshop posters.
2. Review the recently released protocols after having the opportunity to review the public comments on those protocols (comment period ends in early March).
3. Review the input from the IRIS Public Science Meetings (including TBA and ETBE) and how EPA responded to this input in the draft assessments.
4. Review the completed portions of the nearly completed IRIS handbook.¹¹ This key set of protocols would benefit from NRC review.
5. Review an IRIS 2.0 Assessment whenever EPA completes either an assessment for peer review (IRIS step four) or a final assessment (IRIS step seven). Reviewing actual assessments would allow NRC to determine if EPA is institutionally capable of implementing the IRIS 2.0 reforms.

Advocacy appreciates the opportunity to provide input on these important issues. If you want to discuss these issues with my office, please contact Kevin Bromberg of my staff at kevin.bromberg@sba.gov or 202-205-6964.

Sincerely,

/s/

Major Clark
Acting Chief Counsel for Advocacy

/s/

Kevin Bromberg
Assistant Chief Counsel
Office of Advocacy

¹⁰ EPA Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water Proposed Approaches, September 2017, p. 5-1.

¹¹ The handbook contains the instructions for completing systematic review and other protocols underlying the development of IRIS 2.0 assessments.

Copy to: The Honorable Neomi Rao
 Administrator
 Office of Information and Regulatory Affairs
 Office of Management and Budget

Message

From: Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 1/25/2018 9:50:10 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]
CC: Christ, Lisa [Christ.Lisa@epa.gov]
Subject: RE: Perchlorate

No -- that's ok! I look forward to Monday ☺

Jim

From: Burneson, Eric [mailto:Burneson.Eric@epa.gov]
Sent: Thursday, January 25, 2018 4:43 PM
To: Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy (PP)]>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Perchlorate

Thanks Jim: I appreciate you reaching out. We were in the process of creating a track changes version to show how the charge had been modified from the 9/15 version. I will hold off on that but let me know if you think that would be informative.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Kim, Jim H. EOP/OMB [mailto:Ex. 6 Personal Privacy (PP)]
Sent: Thursday, January 25, 2018 4:30 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Perchlorate

Eric,

Looking back through my files and emails -- I see the 9/15/2017 version (emailed by Lisa Christ) is pretty similar to the final charge questions. And I also see the charge question 11.d. basically answers what I was looking for. So no need to trouble yourself, and no need to talk tomorrow. Sorry about the confusion!

Jim

James Kim, Ph.D., DABT
Office of Management and Budget
[Ex. 6 Personal Privacy (PP)]

Message

From: Burneson, Eric [burneson.eric@epa.gov]
Sent: 6/1/2020 5:17:06 PM
To: [Ex. 6 Personal Privacy (PP)]; Christ, Lisa [Christ.Lisa@epa.gov]; Parikh, Pooja [Parikh.Pooja@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]
Subject: Perchlorate

Perchlorate

Parikh, Pooja

ATTORNEY-ADVISER , OGC

Work: [202-564-0839](tel:202-564-0839)

Email: parikh.pooja@epa.gov

IM: parikh.pooja@epa.gov

[Ex. 6 Personal Privacy (PP)]

Mobile:

Email:

IM:

[Ex. 6 Personal Privacy (PP)]

Christ, Lisa

SUPV ENVIRONMENTAL PROTECTION SPEC , OW

Email: christ.lisa@epa.gov

IM: christ.lisa@epa.gov

Wehling, Carrie

ATTORNEY-ADVISER , OGC

Work: [+1 \(202\) 564-5492](tel:+12025645492)

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Work: [202-564-5492](tel:202-564-5492)

Mobile: [Ex. 6 Personal Privacy (PP)]

Email: wehling.carrie@epa.gov

IM: wehling.carrie@epa.gov

Skype for Business

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 6/9/2020 9:40:55 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]
Subject: RE: EO12866: OMB Comments on Perchlorate Notice
Attachments: EO12866_SDWA NPDWR 2040-AF28 FRN Perchlorate Rule 20200609.docx

Vlad;

Attached please find EPA's edits and responses to the consolidated comments received from the Inter Agency Review. We have accepted the majority of recommended edits and have offered alternative language where appropriate.

As we discussed DOJ has requested signature of this action not later than June 18, 2020. We therefore need OMB clearance by June 17.

We can meet to discuss any questions you have regarding the attached document. Thank you for your coordination and your input on this important action.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Friday, June 05, 2020 10:07 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Ex. 5 Deliberative Process (DP)

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Friday, June 5, 2020 9:15 AM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>;

Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad

We received this additional set of EOP comment and we will fold this in with the OMB, SBA and USDA comments. I assume your deadline for inter agency comments was yesterday and there should be no more comments forthcoming. Regarding this afternoon, I am not certain if we need a conversation at this stage as we are still evaluating the comments, but I would like to put a placeholder on your calendar for 3:30 just in case it is needed. I will follow up later this morning to confirm and let you know what if any topics we want to discuss. Does that work?

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**

Sent: Friday, June 05, 2020 8:58 AM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>;

Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks for combining the comments. Unfortunately, I need to throw another curve ball because I received some late comments from an EOP reviewer that I have to pass on. They are attached. You will find that many are technical/stylistic but there are also a couple legal questions. I would appreciate it if you could incorporate these comments and responses into your master passback as well.

Sorry again for the piecemeal submission of comments. Hopefully, it's not a huge inconvenience for you and, if anything, has saved more time than it has cost.

As for chatting, I may have a little time after the EO meeting but I have an EO meeting on another rule at 3:00. We can play by ear but I'm happy to pencil in a chat at 2:30? Would just be me and you (in which case one of us can just call the other) or a broader group requiring a conference line? If we don't have enough time, I'm completely free after 3:00 meeting so would be happy pick think up at, say, 3:30 or 4:00.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Friday, June 5, 2020 8:33 AM

To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>;

Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad: We have combined the three comment documents into a single file and will prepare a passback with this combined file. Are you available after the 12866 meeting with AWWA this afternoon in case we have any questions about the comments?

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**

Sent: Thursday, June 04, 2020 6:05 PM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>;

Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Really sorry but it looks like I jumped the gun more than I had realized; I just received comments from SBA which I wasn't expecting. I'm not sure I agree with all of SBA's comments so, perhaps, once you've reviewed these and other comments we can chat briefly about options. Hopefully these are the last of the comments.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:05 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: 'Parikh, Pooja' <Parikh.Pooja@epa.gov>; 'Christ, Lisa' <Christ.Lisa@epa.gov>; 'Johnson, Ann' <Johnson.Ann@epa.gov>; 'Wehling, Carrie' <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Murphy's Law is alive and well. Just as I clicked send on the message below, I received the attached comments from USDA. Having heard from all the agencies I knew may be interested in perchlorate (DOD, HHS/FDA, NASA, SBA), I did not expect anybody else to submit comments. I would appreciate it if you could incorporate these comments and your responses to them into your passback.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:00 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to characterize the role that cost benefit analysis played in the Administrator's decision in light of this afternoon's call. I'm sure you can guess where my office would stand on the matter.

Vlad

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 6/15/2020 6:35:58 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]
Subject: RE: EO12866: OMB Comments on Perchlorate Notice
Attachments: EO12866 EPA Perchlorate Rule (Combined Comments from OMB 06-12-20)EPA Response 6-15-20.docx

Vlad:

Attached please find a revised FR Notice with responses to comments and edits in response to the Inter Agency Comments. We believe the attached addresses all of the Inter Agency concerns and would like to close out review as soon as possible to facilitate signature and filing of court actions prior to the Consent Decree deadline.

Thank you for your work to facilitate this review. Please let me know if you have any questions

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Friday, June 12, 2020 11:14 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Attached please find some additional comments on the perchlorate notice. I have put them on top of the preliminary set I sent you earlier but highlighted them all in yellow and included "[6/12]" in all of them so you can search on that to find them. Please note that I spoke with USDA and these comments reflect a refined version of their comments below. Let me know if would help to discuss any of this by phone.

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Thursday, June 11, 2020 6:42 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: Re: EO12866: OMB Comments on Perchlorate Notice

I'm going to go ahead and send you the comments I just received from USDA. I'm in the process of running some internal traps to see where OMB stands on these issues but wanted to flag them for you in the meantime. Also, these comments may not be the totality of additional comments I have.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Sent from my iPhone

On Jun 11, 2020, at 6:23 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:

Vlad:

Thank you for transmitting the provisional comments yesterday. We do not require a discussion of the comments. We have drafted a passback/response document. Before I ask for senior level EPA review I wanted to check with you to see if any more comments are forthcoming. You noted that the Inter Agency deadline was COB today, but based on recent experience, I am assuming we should wait until tomorrow morning before assuming that there will be no more comments.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB

Ex. 6 Personal Privacy (PP)

Sent: Wednesday, June 10, 2020 2:07 PM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Eric,

Thanks again for addressing comments so quickly. Please note that I have not heard from all reviewers yet (I gave them until COB Thursday to get back to me) so the attached comments should be seen as provisional. That being said, I have heard back from SBA so wanted to go ahead and pass along their comments to you. I have clearly identified the follow-up comments submitted by SBA in the attached documents. Most are worded as helpful suggestions but let me know if you have any concerns. Also, I have fixed a number of typos but you may want to give the document a careful scrub as part of a final review. I realize that, by sending this document, I have created some version control challenges but I felt it was important to pass along SBA's comments now.

Feel free to give me a call if you want to discuss.

Vlad

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, June 9, 2020 5:41 PM
To: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad;
Attached please find EPA's edits and responses to the consolidated comments received from the Inter Agency Review. We have accepted the majority of recommended edits and have offered alternative language where appropriate.

As we discussed DOJ has requested signature of this action not later than June 18, 2020. We therefore need OMB clearance by June 17.

We can meet to discuss any questions you have regarding the attached document. Thank you for your coordination and your input on this important action.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>
Sent: Friday, June 05, 2020 10:07 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks and that works. Note that I have just gotten off the phone with DOJ regarding whether

[Ex. 5 Deliberative Process (DP)]
[Ex. 5 Deliberative Process (DP)] I am not ready to offer any recommendation on a [Ex. 5 Deliberative Process (DP)]
Ex. 5 Deliberative Process (DP)
[Ex. 5 Deliberative Process (DP)] Of course, SBA just issued a public letter
in the context of the MSGP pushing back on that approach but I may be able to convince them to [Ex. 5 Deliberative Process (DP)]
[Ex. 5 Deliberative Process (DP)]
We can discuss further later today or next week.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Friday, June 5, 2020 9:15 AM
To: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann

<Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad

We received this additional set of EOP comment and we will fold this in with the OMB, SBA and USDA comments. I assume your deadline for inter agency comments was yesterday and there should be no more comments forthcoming.

Regarding this afternoon, I am not certain if we need a conversation at this stage as we are still evaluating the comments, but I would like to put a placeholder on your calendar for 3:30 just in case it is needed. I will follow up later this morning to confirm and let you know what if any topics we want to discuss. Does that work?

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]

Sent: Friday, June 05, 2020 8:58 AM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks for combining the comments. Unfortunately, I need to throw another curve ball because I received some late comments from an EOP reviewer that I have to pass on. They are attached. You will find that many are technical/stylistic but there are also a couple legal questions. I would appreciate it if you could incorporate these comments and responses into your master passback as well.

Sorry again for the piecemeal submission of comments. Hopefully, it's not a huge inconvenience for you and, if anything, has saved more time than it has cost.

As for chatting, I may have a little time after the EO meeting but I have an EO meeting on another rule at 3:00. We can play by ear but I'm happy to pencil in a chat at 2:30? Would just be me and you (in which case one of us can just call the other) or a broader group requiring a conference line? If we don't have enough time, I'm completely free after 3:00 meeting so would be happy pick think up at, say, 3:30 or 4:00.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Friday, June 5, 2020 8:33 AM

To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad: We have combined the three comment documents into a single file and will prepare a passback with this combined file. Are you available after the 12866 meeting with AWWA this afternoon in case we have any questions about the comments?

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]

Sent: Thursday, June 04, 2020 6:05 PM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Really sorry but it looks like I jumped the gun more than I had realized; I just received comments from SBA which I wasn't expecting. I'm not sure I agree with all of SBA's comments so, perhaps, once you've reviewed these and other comments we can chat briefly about options. Hopefully these are the last of the comments.

From: Dorjets, Vlad EOP/OMB
Sent: Thursday, June 4, 2020 5:05 PM
To: 'Burneson, Eric' <Burneson.Eric@epa.gov>
Cc: 'Parikh, Pooja' <Parikh.Pooja@epa.gov>; 'Christ, Lisa' <Christ.Lisa@epa.gov>; 'Johnson, Ann' <Johnson.Ann@epa.gov>; 'Wehling, Carrie' <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Murphy's Law is alive and well. Just as I clicked send on the message below, I received the attached comments from USDA. Having heard from all the agencies I knew may be interested in perchlorate (DOD, HHS/FDA, NASA, SBA), I did not expect anybody else to submit comments. I would appreciate it if you could incorporate these comments and your responses to them into your passback.

From: Dorjets, Vlad EOP/OMB
Sent: Thursday, June 4, 2020 5:00 PM
To: 'Burneson, Eric' <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to

Ex. 5 Deliberative Process (DP)

Vlad

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 8/14/2017 9:50:37 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)] Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]
CC: Johnson, Ann [Johnson.Ann@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]
Subject: RE: Perchlorate charge

Thanks Vlad:

I remained vague about who and how comments on the charge should be submitted after the Draft Report is made available. However, since I restated our commitment to hold a call during the comment period I think we can work that detail out at that time. Thanks again for your help and input.

Eric

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Monday, August 14, 2017 5:35 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>
Cc: Johnson, Ann <Johnson.Ann@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Perchlorate charge

Eric – I got your voicemail. Thanks for instructing interagency reviewers to copy me on their final comments on the draft charge. I meant to ask you to do that but it slipped my mind. I hadn't considered whether they should copy me on comments they send in response to FRN once they have reviewed the report. I imagine that many of them will copy me regardless of what you say but I'm fine with you suggesting to them that they do that too. I'll be around a bit longer if you want to call me back.

From: Burneson, Eric [mailto:Burneson.Eric@epa.gov]
Sent: Monday, August 14, 2017 5:23 PM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>
Cc: Johnson, Ann <Johnson.Ann@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: FW: Perchlorate charge

Caryn:

Would you please distribute the attached Draft Charge to the Federal Inter-Agency participants in last weeks meeting on the perchlorate peer review.

Eric

Inter-Agency Partners:

Thank you for your review and comment on the draft charge for the next perchlorate peer review. We believe that the input we received from you has helped us to communicate more clearly about our analysis and the critical assumptions, strengths and limitations.

Attached is a revised draft charge that responds to the concerns identified in our discussion last Wednesday. In preparing the attached revisions, we tried to better organize the issues and break down complex charge questions into more direct questions. We ask that you review the attached draft charge and provide us with any comments or suggestions by Friday, August 18. Please send comments on the draft charge to myself and Eric Burneson. Please also copy Vlad Dorjets on your comments as well.

After we receive your input our next steps will be as follows:

1. Prepare a revised draft charge that addresses Inter- Agency Input
2. Publish an FRN that announces the availability and requests comment on
 - a. The Draft Charge,
 - b. The Preliminary List of Peer reviewers, and
 - c. Draft Report on Approaches to Inform Derivation of the MCLG
3. We will request public comments on the draft charge and peer reviewers within 21 days of FRN publication. We will schedule Inter Agency call during this period to discuss the revised charge and will ask for any Inter Agency comments on the draft charge to be provided via email.
4. We will request comments on the draft MCLG Approaches Report within 45 days of the FRN Publication. Inter-Agency comments on the draft report should be submitted in accordance with the process identified in the FRN.
5. After addressing comments on the draft charge and Versar's selection of the peer reviewers, we will publish an FRN announcing the peer review panel members, the final charge and the date and location of the public peer review meeting. We will also publish information on how to register to attend and/or provide public comment at the peer review meeting.
6. We will provide public comments on the draft MCLG Approaches Report to peer reviewers for their review and consideration.
7. Peer reviewers will meet in a public meeting in the DC Metro Area (date and specific location TBD).
8. EPA will post the final peer review report in the Docket upon completion.

Thank you for your continued input into this important peer review process

From: Grevatt, Peter
Sent: Monday, August 14, 2017 3:38 PM
To: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>; Burneson, Eric <Burneson.Eric@epa.gov>;
[Ex. 6 Personal Privacy (PP)]
Cc: Schwab, Margo EOP/OMB <[Ex. 6 Personal Privacy (PP)]>; Laity, Jim A. EOP/OMB
<[Ex. 6 Personal Privacy (PP)]>; Mclain, Jennifer <Mclain.Jennifer@epa.gov>; Muellerleile, Caryn
<Muellerleile.Caryn@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>
Subject: RE: Perchlorate charge

Great news Vlad. Thanks again to you, Jim, Jim, Margo and your entire team for all of your help with this! We'll get this out to the interagency reviewers this afternoon.

From: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>
Sent: Monday, August 14, 2017 3:29 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>; [Ex. 6 Personal Privacy (PP)] ✓
Cc: Schwab, Margo EOP/OMB <[Ex. 6 Personal Privacy (PP)]>; Laity, Jim A. EOP/OMB
<[Ex. 6 Personal Privacy (PP)]>; Grevatt, Peter <Grevatt.Peter@epa.gov>; Mclain, Jennifer
<Mclain.Jennifer@epa.gov>; Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>
Subject: RE: Perchlorate charge

Eric,

Thank you for sharing this revised draft charge. I want to thank you for your willingness to engage with OMB and EPA throughout this process and for that thoughtfulness with which you have addressed our comments. OMB does not have any further comments on the charge. Please go ahead and distribute to interagency reviewers (presumably to the people on the invitation list to last week's briefing) for final comments. Also, it may not be a bad idea to let the

interagency reviewers (and OMB) know when the FRN has been published so that they can get the report right away and maximize the time they have to review it.

Vlad

From: Burneson, Eric [mailto:Burneson.Eric@epa.gov]
Sent: Friday, August 11, 2017 3:41 PM
To: Kim, Jim H. EOP/OMB <[Ex. 6 Personal Privacy (PP)] Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>
Cc: Schwab, Margo EOP/OMB <[Ex. 6 Personal Privacy (PP)]>; Laity, Jim A. EOP/OMB <[Ex. 6 Personal Privacy (PP)]>; Grevatt, Peter <Grevatt.Peter@epa.gov>; Mclain, Jennifer <Mclain.Jennifer@epa.gov>; Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>
Subject: RE: Perchlorate charge

Vlad and Jim:

Thank you for helping to facilitate a constructive meeting with our Federal partners this week on the perchlorate peer review. We believe that the input we received from you and our Federal partners has helped us to communicate more clearly about our analysis and the critical assumptions, strengths and limitations.

Attached is a revised draft charge that responds to the concerns identified in our discussion on Wednesday. In preparing the attached revisions, we tried to better organize the issues and break down complex charge questions into more direct questions. Prior to distribution to the other Federal Agencies, we ask that you review the attached charge and let us know if you have any suggestions for better addressing the identified concerns.

Our goal is to have input from the other Federal Agencies by Friday, August 18th so that we can move forward with the next steps in conducting the peer review. Therefore we hope to have your feedback by early next week.

Thanks in advance for your continued input.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Burneson, Eric
Sent: Tuesday, August 08, 2017 7:29 PM
To: 'Kim, Jim H. EOP/OMB' <[Ex. 6 Personal Privacy (PP)]>; Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>
Cc: Schwab, Margo EOP/OMB <[Ex. 6 Personal Privacy (PP)]>; Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>; Laity, Jim A. EOP/OMB <[Ex. 6 Personal Privacy (PP)]>; Grevatt, Peter <Grevatt.Peter@epa.gov>; Mclain, Jennifer <Mclain.Jennifer@epa.gov>
Subject: RE: Perchlorate charge

Jim:

Thanks very much for your comments on the draft peer review charge. We have incorporated your input in the revised draft charge document (dated 8-8-17) that will soon be distributed to Inter Agency partners. To assist your

understanding in how we incorporated your edits we have also prepared the attached response document for your consideration.

Thanks again for your helpful input.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Monday, August 07, 2017 3:45 PM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>
Cc: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: Perchlorate charge

Hi Caryn, Eric and Lynn,

Thank you for your patience as we worked on this. Attached is a version of the charge with our suggestions in tracked changes. Please let me know if you have any questions.

Best regards,
Jim

James Kim, Ph.D., DABT
Office of Management and Budget
[Ex. 6 Personal Privacy (PP)]

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 6/4/2020 9:07:38 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Also received. We will review and incorporate responses as appropriate.

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Thursday, June 04, 2020 5:05 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Murphy's Law is alive and well. Just as I clicked send on the message below, I received the attached comments from USDA. Having heard from all the agencies I knew may be interested in perchlorate (DOD, HHS/FDA, NASA, SBA), I did not expect anybody else to submit comments. I would appreciate it if you could incorporate these comments and your responses to them into your passback.

From: Dorjets, Vlad EOP/OMB
Sent: Thursday, June 4, 2020 5:00 PM
To: 'Burneson, Eric' <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to [Ex. 5 Deliberative Process (DP)]

Ex. 5 Deliberative Process (DP)

Vlad

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 8/3/2017 6:01:20 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]
Subject: RE: Meeting w/ OMB on Perchlorate
Attachments: DRAFT MCLG Approach Charge 08-02-17clean.docx; DRAFT MCLG Approach Charge 08-02-17trackchanges .docx; Perchlorate OMB Briefing_080317.pptx; DRAFT_Study Summary Tables_8_3_17.docx

Vlad:

We are looking forward to our discussion later today regarding the peer review of the draft Perchlorate MCLG Methodologies Document. I will be bringing copies of the attached materials that we have prepared for next week's discussion with the other Federal Agencies. While I do not expect you or your colleagues will have reviewed these prior to our meeting I wanted to get them to you electronically to facilitate any input you may have on these. Our intent is to share the charge and the briefing materials with the other Federal Agencies once we have gotten feedback from you. Thank you for all the helpful input thus far. I look forward to our discussion later today.

Eric

-----Original Message-----

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Thursday, July 27, 2017 3:16 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Meeting w/ OMB on Perchlorate

Eric,

We're all set to meet over here next Thursday, August 3rd, at 4:00 to discuss perchlorate. The meeting will take place in our new offices on the 9th floor of NEOB (Conference Room 9258). Please enter the names of whomever you think may attend in the link below by COB Tuesday.

Ex. 6 Personal Privacy (PP)

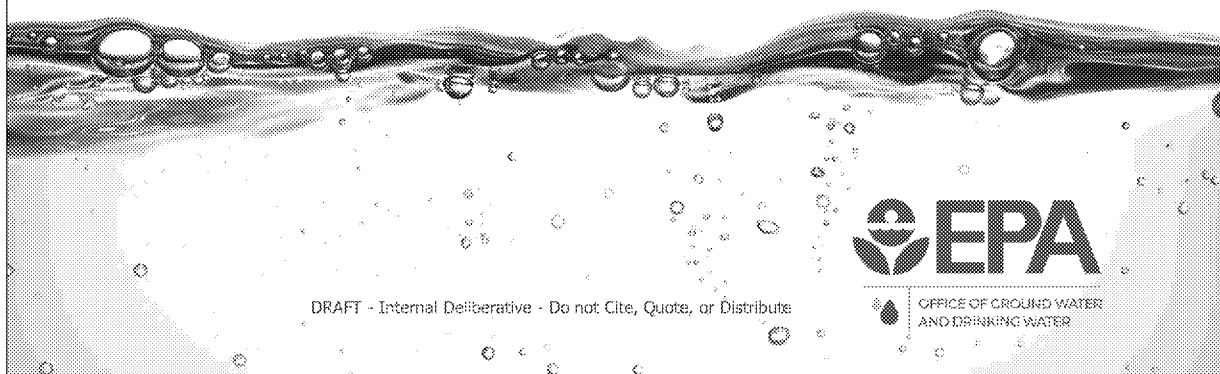
I have attached our comments/questions to help inform your agenda and our discussion in general. Note that these comments are very similar to the ones we sent you after our initial phone call. We understand that you have already answered/addressed some of these questions but we thought it might be helpful to go over them one more time so that we can be clear of your response.

Please don't hesitate to let me know if you have any questions about the attached list.

Vlad

EPA's Draft Approach to Inform the Derivation of an MCLG for Perchlorate in Drinking Water

OMB Briefing | August 3, 2017



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OFFICE OF GROUND WATER
AND DRINKING WATER



BACKGROUND ON THYROID HORMONE PHYSIOLOGY AND CONNECTION TO NEURODEVELOPMENT

DRAFT - Internal Deliberative - Do not Cite, Quote, or Distribute

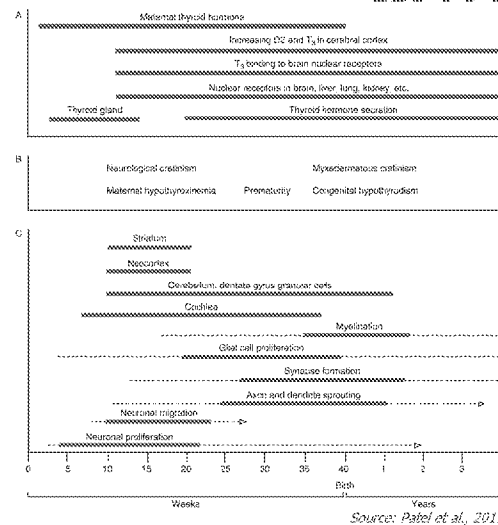
Thyroid Dysfunction Impairs Neurological Development



What does the extensive clinical and experimental evidence tell us?

- Thyroid hormone (TH) essential to normal brain development throughout gestation and early in life
 - TH regulates genes involved in: neurogenesis, cell growth and differentiation, neuronal migration, synaptogenesis, myelination
- TH insufficiency during development causes mental retardation and irreversible sensory, motor, and cognitive deficits
- TH insufficiency can be caused by dietary iodine deficiencies, congenital hypothyroidism, maternal hypothyroidism and hypothyroxinemia
- Early fetal brain development depends on maternal TH; later fetal brain development depends on maternal plus fetal TH
- Timing, duration, severity of TH insufficiency during pregnancy influences types of neurological deficits
- Mild and transient maternal TH insufficiency at the low end of normal reference ranges is associated with neurological impairments in children

(e.g., Simk et al. 2000; Haddow et al. 1999; Pop et al. 1999; 2003; Vermiglio et al. 2004; Koolstra et al. 2006; Korevaar, 2016)



Hypothyroxinemia: Fit-for-Purpose Approach to Perchlorate BBDR



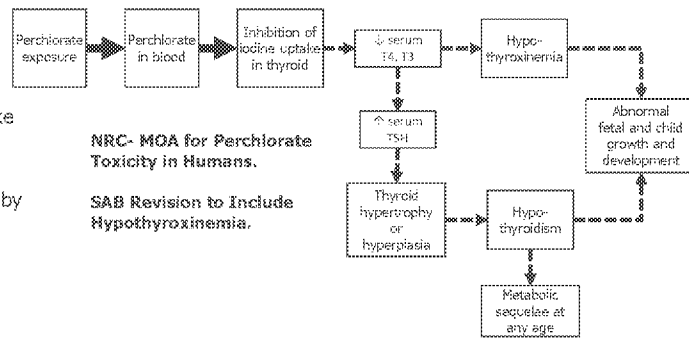
• 2005 NAS/NRC :

- Pregnant women and their fetuses are particularly sensitive populations. Some pregnant women may have a low iodide intake increasing susceptibility.

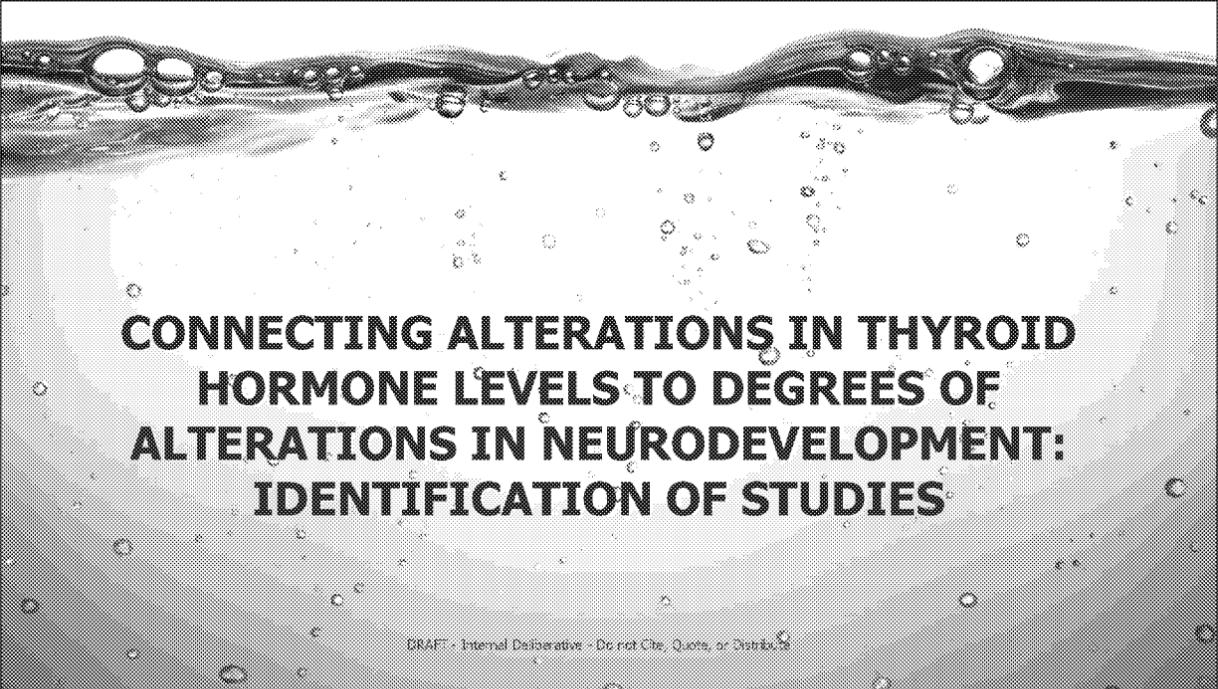
- Recommend inhibition of iodide uptake (IUI) by the thyroid be used as the basis for RfD derivation

• 2013 SAB recommended:

- The EPA should extend the PBPK/PD-IUI model to describe changes in thyroid hormone levels during sensitive life stages. This will provide a key tool to link IUI, thyroid hormone, and neurodevelopmental outcome as reported in the scientific and clinical literature.



- ➡ : Perchlorate-induced outcomes NRC 2005 determined were observed in humans
- ➡ : Outcomes determined by NRC to not be clearly demonstrated in humans exposed to perchlorate, but biologically possible in the absence of adequate compensation
- ... ➡ : Augmented mode of action determined by SAB 2013



**CONNECTING ALTERATIONS IN THYROID
HORMONE LEVELS TO DEGREES OF
ALTERATIONS IN NEURODEVELOPMENT:
IDENTIFICATION OF STUDIES**

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Objective and Protocol Used to Identify Literature



- EPA conducted a review to identify, select, assess, and summarize literature that provided empirical linkages between thyroid hormone changes and neurodevelopmental outcomes as recommended by the SAB.
- The review was conducted in PubMed and Google Scholar.
 - Search strings were developed
 - Searches were restricted to studies published from 2000 to January 2017
- 3 step process to categorize the literature
 - Step 1: Identify studies that would not inform empirical linkage between thyroid hormone and neurodevelopment (Group 3)
 - Step 2: Distinguish between studies containing categorical (Group 2) and continuous function (Group 1) information
 - Step 3: Characterized Group 1 studies using the following:
 - The population for which the dose-response information is available.
 - The endpoint evaluated.
 - The availability of iodine intake data for the study population.
 - The method of thyroid hormone sampling.
 - The timing of the thyroid hormone measurement
 - The size of the study population

Process for Identifying Literature



Search Category	Search Strings ^a
Endpoint: Neurodevelopment	<ul style="list-style-type: none"> • Neurodevelopment AND hypothyroxinemia^b • "Neurodevelopmental effects" AND hypothyroxinemia^b • Hypothyroxinemia AND behavior • Hypothyroxinemia AND behavior AND infant • Hypothyroxinemia AND thyroxine AND behavior AND infant • (Thyroxine OR T4 OR hypothyroxinemia) AND (neurodevelopment OR "mental ability" OR intelligence OR cognition OR cognitive OR motor OR language)
Endpoint: Attention Deficit/Hyperactivity Disorder	<ul style="list-style-type: none"> • "Maternal hypothyroxinemia" AND thyroxine AND ADHD AND infant
Endpoint: Autism	<ul style="list-style-type: none"> • Hypothyroxinemia AND autism^b • Hypothyroxinemia AND thyroxine AND autism AND infant
^a Searches were restricted to studies published from 2000 to January 2017. ^b This search string resulted in more articles than we could reasonably evaluate. Therefore, we constrained the search so that databases searched for those terms only in the title.	

- Identified studies assessing thyroid hormone levels and neurodevelopmental outcomes using PubMed/Google Scholar of epidemiology literature and search strings
- Also reviewed SAB report to confirm literature review captured all studies cited as potential references related to the relationship between thyroid hormone and neurodevelopment, including some published prior to 2000. This step yielded 6 additional papers to evaluate
- 55 studies identified

Group 3 Studies



- All studies are discussed and summarized in the report
- Studies did not provide information on maternal T4 or fT4
- Studies evaluated pregnant women with existing disease (e.g., hypothyroidism)
- Studies were not primary literature (e.g. review articles) and did not provide data on T4 or fT4 or neurodevelopmental outcomes

Group 2 Studies

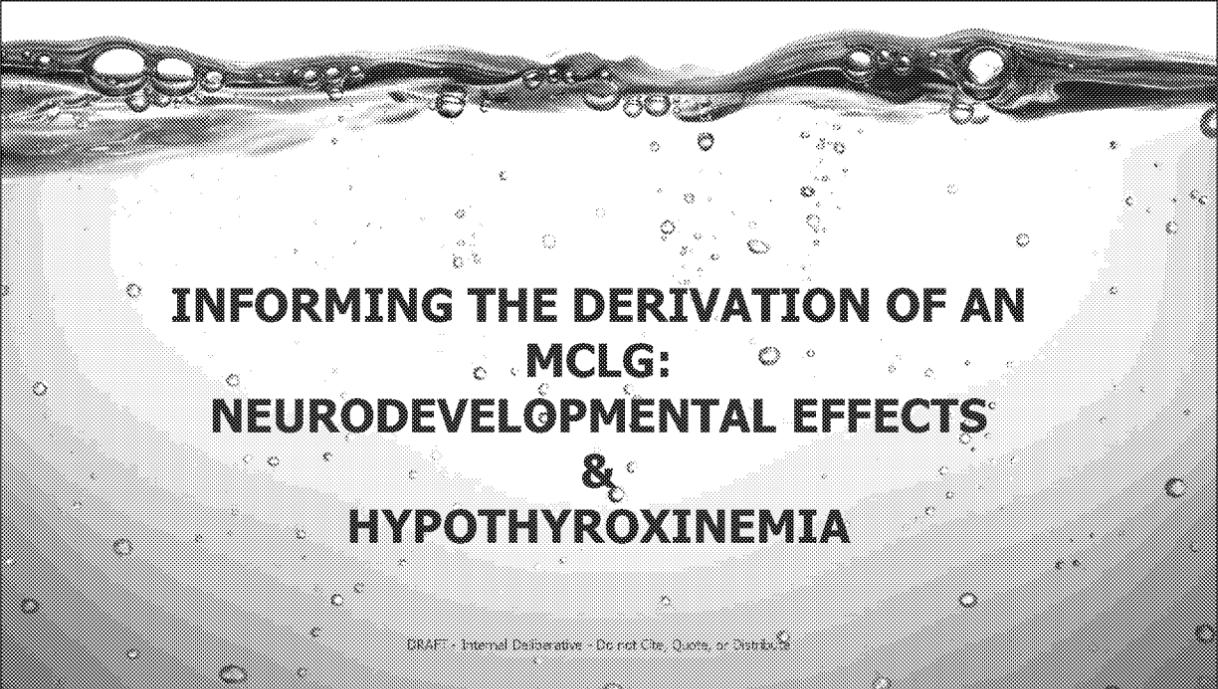


- Studies that provided categorical analyses
 - Example: Analysis of neurodevelopmental outcomes in offspring of mothers with hypothyroxinemia, compared to non-hypothyroxinemic mothers
- Many studies provided multiple neurodevelopmental endpoints for various age groups
- Results for all studies are presented regardless of statistical significance or association between thyroid hormone levels and neurodevelopmental endpoints
- See attached summary table for a presentation of results by neurodevelopmental outcomes (e.g., IQ, BSID)

Group 1 Studies



- Studies that provided data allowing for the derivation of a continuous function relating thyroid hormone levels to a defined change in neurodevelopment.
- As in Group 2, many studies provided multiple neurodevelopmental endpoints for various age groups including:
 - IQ, Bayley Scales, reaction time, expressive language delay, schizophrenia, arithmetic performance, and visual recognition memory
- Results for all studies are summarized in text and presented regardless of statistical significance or relationship
- See attached summary table for a presentation of results by neurodevelopmental outcomes (e.g., IQ, BSID)



**INFORMING THE DERIVATION OF AN
MCLG:
NEURODEVELOPMENTAL EFFECTS
&
HYPOTHYROXINEMIA**

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Predicted Dose of Perchlorate Resulting in a 1 Unit Change in Neurodevelopmental Measure



Dose of Perchlorate ($\mu\text{g}/\text{kg}/\text{day}$)	Endpoint	Study
27.3 – 77.2 ^a	1 point change in IQ	Korevaar et al. (2016)
6.5 – 14.9 ^a	1 point change in IQ	Vermiglio et al. (2004)
2.3 – 5.2 ^a	1 point change in MDI	Pop et al. (2003)
1.9 – 3.8 ^a	1 point change in PDI	Pop et al. (2003)
1.4 – 3.8 ^a	1 point change in PDI	Pop et al. (1999)
2.6 – 6.8 ^a	1 millisecond change in Standard Deviation of Reaction Time	Finken et al. (2013)
0.7 – 0.8 ^b [1%] 3.8 – 3.9 ^b [5%]	1% or 5% Increase in Proportion of Hypothyroxinemic Pregnant Women	N/A

^aLow Iodide intake ($\approx 75 \mu\text{g}/\text{day}$); Range based on using the central and outer bound 95% CI Beta.
^bRange based on gestational week used to perform the analysis (12 to 16 weeks).

Characterization of Uncertainty and Variability in the Report



- Some study results did not show statistical significance
- Relationships analyzed using FT4 levels at only a single point during pregnancy
- Several continuous functions are based on data digitized from figures
- True FT4 levels at various percentiles in the distribution around the median output on the BBDR model (shape of the distribution)
- None of the current studies used to quantify the defined change in neurodevelopment are based on a U.S. population
- Iodine intake of study populations are not always known
- Thyroid hormone assay results obtained at different times or in different countries



APPENDIX A: BBDR MODEL

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Overview of January 2017 Draft BBDR Model



"... EPA undertook the development of biologically based dose-response models for the effect of perchlorate on thyroid hormones in women and their offspring during end of term pregnancy and lactation."

"The model represents a major effort to utilize quantitative computational modeling to capture available scientific information describing perchlorate inhibition of the sodium iodide symporter (NIS) and the relationships between iodine intake and circulating levels of thyroid hormones including T4 and T3."

"Thyroid hormones, in turn, are major determinants of neurodevelopment during pregnancy, infancy, and childhood."

"Notable strengths of this effort are that it is based upon the consensus mode of action (MOA) for perchlorate inhibition of iodine uptake, uses human iodine and perchlorate toxicokinetic data, addresses sensitive life stages, and is designed to be protective of serious, unambiguous adverse health effects known to occur in humans (i.e., neurodevelopmental deficits) associated with thyroid hormone deficiencies."

(Peer Review Summary Report, 2017)

Peer Review Recommendations



EPA contractor conducted an independent, external peer review of EPA's draft BBDR model and draft model report.

Peer reviewers were responsible only for evaluating the quality of the science and were not asked to make any regulatory recommendations or to reach consensus in either their deliberations or written comments.

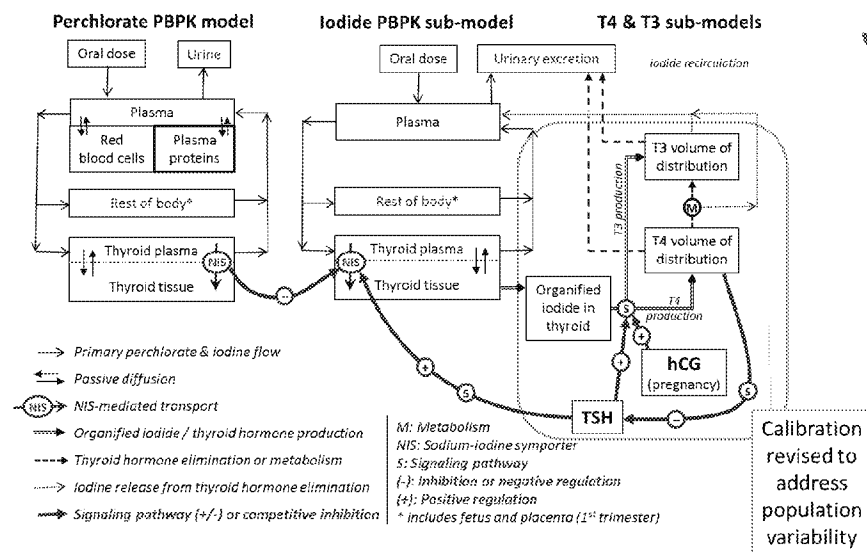
Summary of recommendations based on 7 charge questions (See appendix for complete text of charge, panelist responses and EPA actions.):

Ex. 5 Deliberative Process (DP)

Summary of recommendations:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)



Ex. 5 Deliberative Process (DP)

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 6/4/2020 9:06:41 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Received.
Thanks Vlad

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Thursday, June 04, 2020 5:00 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to [Ex. 5 Deliberative Process (DP)]

Ex. 5 Deliberative Process (DP)

Vlad

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 6/4/2020 3:39:41 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Subject: RE: Perchlorate

Thanks Vlad. I look forward to our conversation at 4:00 today.

From: Dorjets, Vlad EOP/OMB [mailto:**Ex. 6 Personal Privacy (PP)**]
Sent: Thursday, June 04, 2020 10:50 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>
Subject: Perchlorate

Eric – Both HHS and DOD let me know this morning that they don't have any comments on the perchlorate notice. I'll wait for this afternoon's call in case I want to capture anything we hear in OMB's comments but expect to send you whatever I have at some point tonight.

Appointment

From: Burneson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cacb9a8d49f49af80531e9e2ccb9018-eburneso]
Sent: 5/28/2020 9:36:27 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]
Subject: Perchlorate
Location: Skype Meeting
Start: 6/1/2020 5:00:00 PM
End: 6/1/2020 6:00:00 PM
Show Time As: Tentative

Join Skype Meeting

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Toll number: **Ex. 6 Personal Privacy (PP)** Dial-in Number English (United States)

[Find a local number](#)

Conference ID: **Ex. 6 Personal Privacy (PP)**

[Forgot your dial-in PIN?](#) | [Help](#)

From: Dorjets, Vlad EOP/OMB <**Ex. 6 Personal Privacy (PP)**>
Sent: Thursday, May 28, 2020 12:26 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>
Subject: RE: Perchlorate

Let's go with 1:00 if that works for you and thanks for setting this up. And to be clear, this is just an informal chat to understand the thinking behind some of the decisions in the document. I don't plan to provide any comments at that time but simply ask a few questions to help inform my thinking as I prepare comments.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Thursday, May 28, 2020 12:22 PM
To: Dorjets, Vlad EOP/OMB <**Ex. 6 Personal Privacy (PP)**>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>
Subject: RE: Perchlorate

Vlad; I agree that it would be helpful to discuss the legal considerations involved in this action (including the timeline for clearing the action NLT June 17). I have checked with our General Counsel's Office representative and she is available at either 11am or 1 pm on Monday. Please let me know if you have a preference for either time and I can set up a meeting.
Eric

From: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>

Sent: Thursday, May 28, 2020 11:42 AM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Subject: Perchlorate

I imagine that a lot of what was drafted in the perchlorate rule is a result of very deliberate legal consideration. I think it would help me to understand whether [Ex. 5 Deliberative Process (DP)]

[Ex. 5 Deliberative Process (DP)] I expect to be done reading the document tomorrow (too many other things going on that prevent me from reading it straight through) so perhaps we could chat sometime on Monday?

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 8/1/2017 7:53:06 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]
Subject: RE: Interagency Briefing on Perchlorate

Thanks Vlad:

I will work with Caryn to send out an advance message for the meeting on August 9. Regarding the list for the EPA attendees at the OMB discussion on August 3, you have the correct participants and we do not anticipate adding any more attendees.
Eric

-----Original Message-----

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Tuesday, August 01, 2017 3:43 PM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: Interagency Briefing on Perchlorate

Caryn - No worries at all. I received the invitation and accepted.

Eric - I'm start to get some incoming questions about the meeting (which led to my confusion and earlier email). It may not be a bad idea for you (via Caryn) to send out a short message to everybody on the invitation that if they would like to raise specific questions or concerns for EPA to address they should send them to Caryn (?) and copy me. It may also be a good idea to let everybody know that, out of the interest of time, comments on the charge questions will be due two (?) days after the briefing. Happy to discuss and look forward to our own meeting later this week. Speaking of which, I show you, Peter, Ann, David Bussard, Lynn Flowers, and Pamela Noyes as attending. I just sent those names to the security office. You can certainly add additional people but please let me know if you do that because I'll have to send that person's info separately.

-----Original Message-----

From: Muellerleile, Caryn [mailto:Muellerleile.Caryn@epa.gov]
Sent: Tuesday, August 1, 2017 3:20 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: Interagency Briefing on Perchlorate

I am so sorry for not sending you the invite sooner! I did send it to everyone else on the list, including Jim L., last Friday but failed to add your name. You should have received the invite just now, it is planned for Aug. 9 from 3-5 p.m. at EPA in the East building.

Caryn

-----Original Message-----

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Tuesday, August 01, 2017 3:14 PM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>
Cc: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Interagency Briefing on Perchlorate

Caryn,

I just wanted to circle back around about the interagency briefing on perchlorate. If I recall correctly, you're going to send a formal invitation, right? Is that still the plan? If so, can you let me know when you expect to do that? I've already told a handful of reviewers that there would be such a meeting so I'd like to get it on people's schedules so they can plan around it. Also, when you send out the invitation, you may want to let reviewers when comments on the charge questions will be due (two days after meeting?) so that people can plan accordingly. Happy to discuss with you or Eric at your convenience.

Vlad

Appointment

From: Burneson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cacb9a8d49f49af80531e9e2ccb9018-eburneso]
Sent: 6/4/2020 12:36:16 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: Meeting Forward Notification: Call w/ DOJ re Perchlorate
Start: 6/4/2020 1:00:00 PM
End: 6/4/2020 1:30:00 PM
Show Time As: Busy

Your meeting was forwarded

Burneson, Eric has forwarded your meeting request to additional people.

Meeting

Call w/ DOJ re Perchlorate

Meeting Time

Thursday, June 04, 2020 4:00 PM - Thursday, June 04, 2020 5:00 PM

Recipients

Wehling, Carrie

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 4/14/2020 6:41:16 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: Some Questions Not Related to Lead-Free Pipes

Vlad I think this is a good list of discussion topics for a call. You can call me at [Ex. 6 Personal Privacy (PP)] or my office phone which is forwarded to my office phone.
Incidentally I just dialed [Ex. 6 Personal Privacy (PP)] and Victoria answered the phone. Did I enter your phone number incorrectly into my cell phone?

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Tuesday, April 14, 2020 2:17 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Some Questions Not Related to Lead-Free Pipes

Eric,

First, I understand from the Steam Electric ELG team that OGWDW is not planning on submitting the bladder cancer / bromide study (I don't recall the author of the top of my head) for peer review at this time. I don't have any opinion on that (I have already provided guidance to OST on how they can and cannot rely on the study for ELG) but ask that if and when you decide to submit the study for peer review, we would like an opportunity to review the charge questions.

Second, could you let me know, for planning purposes, what your working timeline is for LCR? I saw that there was a rather aggressive date included in the draft Unified Agenda but wasn't sure to what extent that accurately reflected the reality. Actually, the same could be said for the PFAS Reg Det timeline. What are your plans for that?

Third, is there any update you can give me on perchlorate?

Thanks and let me know if it would make sense for us to discuss any of this by phone.

Vlad

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 8/8/2017 11:27:54 PM
To: Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]; Flowers, Lynn [Flowers.Lynn@epa.gov]
CC: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Grevatt, Peter [Grevatt.Peter@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]
Subject: RE: Perchlorate charge
Attachments: DRAFT MCLG Approach Charge 08-08-17.docx; DRAFT MCLG Approach Charge 08-02-17_OMB_EPAsponses.docx

Jim:

Thanks very much for your comments on the draft peer review charge. We have incorporated your input in the revised draft charge document (dated 8-8-17) that will soon be distributed to Inter Agency partners. To assist your understanding in how we incorporated your edits we have also prepared the attached response document for your consideration.

Thanks again for your helpful input.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Kim, Jim H. EOP/OMB [mailto:[Ex. 6 Personal Privacy (PP)]]
Sent: Monday, August 07, 2017 3:45 PM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>
Cc: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: Perchlorate charge

Hi Caryn, Eric and Lynn,

Thank you for your patience as we worked on this. Attached is a version of the charge with our suggestions in tracked changes. Please let me know if you have any questions.

Best regards,
Jim

James Kim, Ph.D., DABT
Office of Management and Budget
[Ex. 6 Personal Privacy (PP)]

Message

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 7/17/2017 1:50:32 PM
To: Schuck, Tracey [Schuck.Tracey@epa.gov]
Subject: Fwd: Perchlorate presentation slides and charge for OMB briefing tomorrow
Attachments: OMB Comments on Perchlorate Briefing; ATT00001.htm

Sent from my iPhone

Begin forwarded message:

From: "Muellerleile, Caryn" <Muellerleile.Caryn@epa.gov>
Date: July 14, 2017 at 8:53:42 AM EDT
To: "Burneson, Eric" <Burneson.Eric@epa.gov>, "Olson, Daniel" <Olson.Daniel@epa.gov>, "Hafez, Ahmed" <Hafez.Ahmed@epa.gov>
Cc: "Huff, Lisa" <Huff.Lisa@epa.gov>
Subject: RE: Perchlorate presentation slides and charge for OMB briefing tomorrow

I just received the attached from Vlad – sorry that I didn't get these too you sooner.

Caryn Muellerleile
Regulatory Management Division
Office of Policy
US Environmental Protection Agency
1200 Pennsylvania Ave NW (1803A)
Washington, DC 20460
(202) 564-2855
muellerleile.caryn@epa.gov

From: Burneson, Eric
Sent: Friday, July 14, 2017 8:52 AM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>; Hafez, Ahmed <Hafez.Ahmed@epa.gov>
Cc: Huff, Lisa <Huff.Lisa@epa.gov>
Subject: RE: Perchlorate presentation slides and charge for OMB briefing tomorrow

Caryn:

Attached please find a new presentation for use at next week's meeting and the draft charge (unchanged from the last version you had). Please forward these materials to our Federal partners in advance of the meeting on Tuesday.

Thanks for your assistance in setting up the discussion.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Muellerleile, Caryn
Sent: Monday, July 10, 2017 2:51 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>; Hafez, Ahmed <Hafez.Ahmed@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>
Subject: FW: Perchlorate presentation slides and charge for OMB briefing tomorrow

Just checking in – will you have updated versions of these materials to share for the 7/18 meeting? I've been asked when those will be distributed.

Caryn
564-2855

From: Christ, Lisa
Sent: Wednesday, June 28, 2017 4:39 PM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>
Cc: Burneson, Eric <Burneson.Eric@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>; Hafez, Ahmed <Hafez.Ahmed@epa.gov>
Subject: Perchlorate presentation slides and charge for OMB briefing tomorrow

Hi Caryn,
Attached is the slide deck for the perchlorate briefing and the draft charge for discussion.
Let me know if you need anything else.
Lisa

Appointment

From: Burneson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cacb9a8d49f49af80531e9e2ccb9018-eburneso]
Sent: 6/5/2020 4:07:11 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]
Subject: EO12866: OMB Comments on Perchlorate Notice
Location: Skype Meeting
Start: 6/5/2020 7:30:00 PM
End: 6/5/2020 8:00:00 PM
Show Time As: Tentative

Vlad can we discuss two topics regarding the comments on the perchlorate notice?

: **Ex. 5 Deliberative Process (DP)**

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Toll number: [Ex. 6 Personal Privacy (PP)] access code: [Ex. 6 Personal Privacy (PP)] Dial-in Number) English (United States)

[Find a local number](#)

Conference ID: [Ex. 6 Personal Privacy (PP)] (same as access code above)

[Forgot your dial-in PIN?](#) | [Help](#)

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]

Sent: Friday, June 05, 2020 10:07 AM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>;

Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks and that works. Note that I have just gotten off the phone with DOJ regarding whether this notice is [Ex. 5 Deliberative Process (DP)]

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) I am not ready to offer any recommendation on **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

of

course, SBA just issued a public letter in the context of the MSGP pushing back on that approach but I may be able to

convince them to

Ex. 5 Deliberative Process (DP)

We can discuss further later today or next week.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Friday, June 5, 2020 9:15 AM

To: Dorjets, Vlad EOP/OMB <[REDACTED]> **Ex. 6 Personal Privacy (PP)**

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>;

Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad

We received this additional set of EOP comment and we will fold this in with the OMB, SBA and USDA comments. I assume your deadline for inter agency comments was yesterday and there should be no more comments forthcoming. Regarding this afternoon, I am not certain if we need a conversation at this stage as we are still evaluating the comments, but I would like to put a placeholder on your calendar for 3:30 just in case it is needed. I will follow up later this morning to confirm and let you know what if any topics we want to discuss. Does that work?

From: Dorjets, Vlad EOP/OMB <[REDACTED]> **Ex. 6 Personal Privacy (PP)**

Sent: Friday, June 05, 2020 8:58 AM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>;

Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks for combining the comments. Unfortunately, I need to throw another curve ball because I received some late comments from an EOP reviewer that I have to pass on. They are attached. You will find that many are technical/stylistic but there are also a couple legal questions. I would appreciate it if you could incorporate these comments and responses into your master passback as well.

Sorry again for the piecemeal submission of comments. Hopefully, it's not a huge inconvenience for you and, if anything, has saved more time than it has cost.

As for chatting, I may have a little time after the EO meeting but I have an EO meeting on another rule at 3:00. We can play by ear but I'm happy to pencil in a chat at 2:30? Would just be me and you (in which case one of us can just call the other) or a broader group requiring a conference line? If we don't have enough time, I'm completely free after 3:00 meeting so would be happy pick think up at, say, 3:30 or 4:00.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Friday, June 5, 2020 8:33 AM

To: Dorjets, Vlad EOP/OMB <[REDACTED]> **Ex. 6 Personal Privacy (PP)**

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>;

Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad: We have combined the three comment documents into a single file and will prepare a passback with this combined file. Are you available after the 12866 meeting with AWWA this afternoon in case we have any questions about the comments?

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**

Sent: Thursday, June 04, 2020 6:05 PM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Really sorry but it looks like I jumped the gun more than I had realized; I just received comments from SBA which I wasn't expecting. I'm not sure I agree with all of SBA's comments so, perhaps, once you've reviewed these and other comments we can chat briefly about options. Hopefully these are the last of the comments.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:05 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: 'Parikh, Pooja' <Parikh.Pooja@epa.gov>; 'Christ, Lisa' <Christ.Lisa@epa.gov>; 'Johnson, Ann' <Johnson.Ann@epa.gov>; 'Wehling, Carrie' <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Murphy's Law is alive and well. Just as I clicked send on the message below, I received the attached comments from USDA. Having heard from all the agencies I knew may be interested in perchlorate (DOD, HHS/FDA, NASA, SBA), I did not expect anybody else to submit comments. I would appreciate it if you could incorporate these comments and your responses to them into your passback.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:00 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

Vlad

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 5/27/2020 6:59:43 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Subject: RE: Perchlorate

Yes a regulatory determination is a far simpler notice than a rule making.

-----Original Message-----

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: Wednesday, May 27, 2020 2:57 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Perchlorate

I've been so happy as when I saw the document is only 44 pages. Am already a third of the way through.

Sent from my iPhone

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 7/14/2017 1:12:24 PM
To: Flowers, Lynn [Flowers.Lynn@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Huff, Lisa [Huff.Lisa@epa.gov]; Olson, Daniel [Olson.Daniel@epa.gov]; Hafez, Ahmed [Hafez.Ahmed@epa.gov]; Strong, Jamie [Strong.Jamie@epa.gov]; Miller, Gregory [Miller.Gregory@epa.gov]
CC: Schlosser, Paul [Schlosser.Paul@epa.gov]; Lavoie, Emma [Lavoie.Emma@epa.gov]; Bussard, David [Bussard.David@epa.gov]; Morozov, Viktor [Morozov.Viktor@epa.gov]
Subject: RE: more ORD comments for consideration - Perchlorate OMB draft briefing
Attachments: OMB Comments on Perchlorate Briefing

Folks:

OP just forwarded the attached message from OMB regarding the upcoming briefing. I will set up a call to discuss how we will respond to OMB's request in the attached

From: Burneson, Eric
Sent: Thursday, July 13, 2017 2:53 PM
To: Flowers, Lynn <Flowers.Lynn@epa.gov>; Mclain, Jennifer <Mclain.Jennifer@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>; Hafez, Ahmed <Hafez.Ahmed@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Miller, Gregory <Miller.Gregory@epa.gov>
Cc: Schlosser, Paul <Schlosser.Paul@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>
Subject: RE: more ORD comments for consideration - Perchlorate OMB draft briefing

Attached please find the revised presentation that we propose to utilize for Tuesday's briefing with OMB and other Federal Agencies. We have addressed many of the recommended changes that Lynn conveyed in the email below

- We moved the detailed presentation of the peer review recommendations and actions taken to the appendix and added summary slides describing the peer review recommendations and model changes.
- We decided not to insert a results slide (Table 9) as the focus of the peer review is not on the results of the modeling and literature review but on the scientific basis for that work.
- We also decided not to include written descriptions of why we did not incorporate each peer review recommendation

Our expectations are that ORD will:

- Take the lead in presenting slides 6 -10 (OW will present slides 1 -5 and slides 11-18)
- Lead in responding to technical questions about modifications to the BBDR Model
- Assist in responding to questions about perchlorate's mode of action
- Assist in discussing any potential changes to the draft peer review charge questions

We greatly appreciate your assistance with this important effort.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Flowers, Lynn

Sent: Tuesday, July 11, 2017 5:19 PM

To: Mclain, Jennifer <Mclain.Jennifer@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Olson, Daniel <Olson.Daniel@epa.gov>; Hafez, Ahmed <Hafez.Ahmed@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Miller, Gregory <Miller.Gregory@epa.gov>

Cc: Schlosser, Paul <Schlosser.Paul@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>

Subject: more ORD comments for consideration - Perchlorate OMB draft briefing

Hi everyone – hope this is helpful. We all put our brains together over the last two hours. I know there isn't a lot of time. I don't think it would be bad to get slides to them by Thursday. My two cents.

Meeting question : Can we pin down what your expectations for ORD are for the meeting with respect to the slides?

Slides: All in agreement here to start with slides 13 and 14. Use the color-coded version of the model. I think you have it....

Then see "1)" below re: why we didn't respond to all the recommendations. Maybe have a general slide with bullets as Paul laid out for why some things weren't acted on. This would complement the slide on what WAS acted on – before diving into the weeds.

It is tough to look at the peer review slides. What about organizing them this way:

- 1) List comments to which we responded by making changes
- 2) List comments to which we did not respond, explain why. Some can be simply: not enough time.
- 3) List comments for which no change was needed (blue in current draft).

Supply the charge separately for reference or put charge in appendix. Can this be done quickly? It's just SO hard to follow and so many many slides.

Could include a results slide:

We could include the new Table 9, which I'm copying below as results. "pTSH=1" is full feedback, =0 is turned off. Values are fT4 (difference from control)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Lynn Flowers, PhD, DABT
Associate Director for Science
Office of Science Policy
US EPA
Washington, DC
202-564-6293

From: Flowers, Lynn
Sent: Tuesday, July 11, 2017 1:54 PM
To: Huff, Lisa <Huff.Lisa@epa.gov>; McLain, Jennifer <McLain.Jennifer@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Miller, Gregory <Miller.Gregory@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Cc: Olson, Daniel <Olson.Daniel@epa.gov>; Hafez, Ahmed <Hafez.Ahmed@epa.gov>
Subject: RE: Perchlorate OMB draft briefing

Some *initial* comments for you to consider now.

Based on what I heard OMB asking for at the last meeting. I am a little concerned that

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

I also suggest that slides 13 and 14 should be moved up to the very beginning. Explain the bottom line and then come back to the specifics of the charge and recommendations would seem to be a better way to go.

Back to the original asks – here is my list from Jun 29:

- Main BBDR modeling issues:

- 1) Specifically, which Jan 2017 peer review recommendations were addressed and which were not addressed? DONE - question based on **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

– this sentence is on slide 13 and I would suggest that it be revised. *OMB asked how would you know which recommendations would have the biggest influence? See suggested edits.*

- 2) **Ex. 5 Deliberative Process (DP)** *I don't see that this is addressed. Suggest a slide.*
- 3) How will the model be released to be the most transparent for reviewers? *Perhaps address orally?*

Ex. 5 Deliberative Process (DP)

Hope this is helpful. I know we have some more comments to share a little later today.
Lynn

Lynn Flowers, PhD, DABT
Associate Director for Science
Office of Science Policy
US EPA
Washington, DC
202-564-6293

From: Huff, Lisa

Sent: Tuesday, July 11, 2017 12:36 PM

To: McClain, Jennifer <McClain.Jennifer@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Miller, Gregory <Miller.Gregory@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>

Cc: Olson, Daniel <Olson.Daniel@epa.gov>; Hafez, Ahmed <Hafez.Ahmed@epa.gov>

Subject: Perchlorate OMB draft briefing

Per our conversation earlier, attached is the draft presentation for the upcoming briefing with OMB on 7/18 – please review and provide your comments at your earliest convenience since OMB has requested that we provide them with the briefing tomorrow.

Note – we are working on the orientation of the image on slide 14 but I wanted to go ahead and send the slides to you while we are doing that to give you the most time for review possible.

Thanks,

Lisa Foersom Huff

Associate Branch Chief
Targeting and Analysis Branch
Standards and Risk Management Division
Office of Groundwater and Drinking Water
U.S. EPA
EPA East Bldg. Rm. 2357 H
202-566-0787

Message

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 7/13/2017 8:15:46 PM
To: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]
CC: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; James_H_Kim [Ex. 6 Personal Privacy (PP)]
Subject: OMB Comments on Perchlorate Briefing
Attachments: EPA Perchlorate - OMB comments 7-6-17.docx

Caryn,

Attached please find OMB's comments on EPA's recent briefing on the Perchlorate peer review process and on efforts to regulate percholorate in general. To the extent that these comments can be address in Tuesday's interagency briefing, we woud find that helpful. Otherwise, we can discuss these items offline with you.

Don't hesitate to let us know if you have any questions.

Vlad

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 5/1/2020 6:54:42 PM
To: Dorjets, Vlad EOP/OMB Ex. 6 Personal Privacy (PP)
Subject: RE: Perchlorate

Yes Vlad we are close to transmitting a notice to OMB. I will give you a call to discuss.

From: Dorjets, Vlad EOP/OMB <Ex. 6 Personal Privacy (PP)>
Sent: Friday, May 01, 2020 2:23 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: Perchlorate

Eric – I just wanted to check in to see if there is any update you could provide me on the status of perchlorate.

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 6/16/2020 1:59:35 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks Vlad

From: Dorjets, Vlad EOP/OMB [mailto:Ex. 6 Personal Privacy (PP)]
Sent: Tuesday, June 16, 2020 9:24 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

I was writing to you when you sent this. I hadn't forgotten about timing considerations. I can appreciate the pressure you must be under though.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, June 16, 2020 9:22 AM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad
Based on our conversation yesterday I am anticipating word this morning regarding readiness for clearance. As you know we need signature tomorrow to facilitate DOJ's court filing Thursday.
Please let me know if your timeline has changed.
Eric

From: Dorjets, Vlad EOP/OMB [mailto:Ex. 6 Personal Privacy (PP) EOP]
Sent: Monday, June 15, 2020 2:41 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Received, thanks. I'll circulate and start reviewing right away.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Monday, June 15, 2020 2:36 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP) EOP]
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad:
Attached please find a revised FR Notice with responses to comments and edits in response to the Inter Agency Comments. We believe the attached addresses all of the Inter Agency concerns and would like to close out review as soon as possible to facilitate signature and filing of court actions prior to the Consent Decree deadline.

Thank you for your work to facilitate this review. Please let me know if you have any questions

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB [mailto:] **Ex. 6 Personal Privacy (PP) EOP**
Sent: Friday, June 12, 2020 11:14 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Attached please find some additional comments on the perchlorate notice. I have put them on top of the preliminary set I sent you earlier but highlighted them all in yellow and included "[6/12]" in all of them so you can search on that to find them. Please note that I spoke with USDA and these comments reflect a refined version of their comments below. Let me know if would help to discuss any of this by phone.

From: Dorjets, Vlad EOP/OMB <] **Ex. 6 Personal Privacy (PP) EOP**
Sent: Thursday, June 11, 2020 6:42 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: Re: EO12866: OMB Comments on Perchlorate Notice

I'm going to go ahead and send you the comments I just received from USDA. I'm in the process of running some internal traps to see where OMB stands on these issues but wanted to flag them for you in the meantime. Also, these comments may not be the totality of additional comments I have.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Sent from my iPhone

On Jun 11, 2020, at 6:23 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:

Vlad:

Thank you for transmitting the provisional comments yesterday. We do not require a discussion of the comments. We have drafted a passback/response document. Before I ask for senior level EPA review I

wanted to check with you to see if any more comments are forthcoming. You noted that the Inter Agency deadline was COB today, but based on recent experience, I am assuming we should wait until tomorrow morning before assuming that there will be no more comments.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB [mailto:Vlad.Dorjets@epa.gov] **Ex. 6 Personal Privacy (PP) EOP**
Sent: Wednesday, June 10, 2020 2:07 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Eric,

Thanks again for addressing comments so quickly. Please note that I have not heard from all reviewers yet (I gave them until COB Thursday to get back to me) so the attached comments should be seen as provisional. That being said, I have heard back from SBA so wanted to go ahead and pass along their comments to you. I have clearly identified the follow-up comments submitted by SBA in the attached documents. Most are worded as helpful suggestions but let me know if you have any concerns. Also, I have fixed a number of typos but you may want to give the document a careful scrub as part of a final review. I realize that, by sending this document, I have created some version control challenges but I felt it was important to pass along SBA's comments now.

Feel free to give me a call if you want to discuss.

Vlad

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, June 9, 2020 5:41 PM
To: Dorjets, Vlad EOP/OMB <Vlad.Dorjets@epa.gov> **Ex. 6 Personal Privacy (PP) EOP**
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad;

Attached please find EPA's edits and responses to the consolidated comments received from the Inter Agency Review. We have accepted the majority of recommended edits and have offered alternative language where appropriate.

As we discussed DOJ has requested signature of this action not later than June 18, 2020. We therefore need OMB clearance by June 17.

We can meet to discuss any questions you have regarding the attached document. Thank you for your coordination and your input on this important action.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB [mailto:**Ex. 6 Personal Privacy (PP) EOP**]
Sent: Friday, June 05, 2020 10:07 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks and that works. Note that I have just gotten off the phone with DOJ regarding whether this notice is **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

I am not ready to offer any recommendation on **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Of course, SBA just issued a public letter in the context of the MSGP pushing back on that approach but I may be able to convince them to **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

We can discuss further later today or next week.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Friday, June 5, 2020 9:15 AM
To: Dorjets, Vlad EOP/OMB <**Ex. 6 Personal Privacy (PP) EOP**>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>
Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad

We received this additional set of EOP comment and we will fold this in with the OMB, SBA and USDA comments. I assume your deadline for inter agency comments was yesterday and there should be no more comments forthcoming.

Regarding this afternoon, I am not certain if we need a conversation at this stage as we are still evaluating the comments, but I would like to put a placeholder on your calendar for 3:30 just in case it is needed. I will follow up later this morning to confirm and let you know what if any topics we want to discuss. Does that work?

From: Dorjets, Vlad EOP/OMB [mailto:**Ex. 6 Personal Privacy (PP) EOP**]
Sent: Friday, June 05, 2020 8:58 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks for combining the comments. Unfortunately, I need to throw another curve ball because I received some late comments from an EOP reviewer that I have to pass on. They are attached. You will find that many are technical/stylistic but there are also a couple legal questions. I would appreciate it if you could incorporate these comments and responses into your master passback as well.

Sorry again for the piecemeal submission of comments. Hopefully, it's not a huge inconvenience for you and, if anything, has saved more time than it has cost.

As for chatting, I may have a little time after the EO meeting but I have an EO meeting on another rule at 3:00. We can play by ear but I'm happy to pencil in a chat at 2:30? Would just be me and you (in which case one of us can just call the other) or a broader group requiring a conference line? If we don't have enough time, I'm completely free after 3:00 meeting so would be happy pick think up at, say, 3:30 or 4:00.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Friday, June 5, 2020 8:33 AM

To: Dorjets, Vlad EOP/OMB <[redacted] Ex. 6 Personal Privacy (PP) EOP >

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad: We have combined the three comment documents into a single file and will prepare a passback with this combined file. Are you available after the 12866 meeting with AWWA this afternoon in case we have any questions about the comments?

From: Dorjets, Vlad EOP/OMB <[redacted] Ex. 6 Personal Privacy (PP) EOP >

Sent: Thursday, June 04, 2020 6:05 PM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Really sorry but it looks like I jumped the gun more than I had realized; I just received comments from SBA which I wasn't expecting. I'm not sure I agree with all of SBA's comments so, perhaps, once you've reviewed these and other comments we can chat briefly about options. Hopefully these are the last of the comments.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:05 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: 'Parikh, Pooja' <Parikh.Pooja@epa.gov>; 'Christ, Lisa' <Christ.Lisa@epa.gov>; 'Johnson, Ann' <Johnson.Ann@epa.gov>; 'Wehling, Carrie' <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Murphy's Law is alive and well. Just as I clicked send on the message below, I received the attached comments from USDA. Having heard from all the agencies I knew may be interested in perchlorate (DOD, HHS/FDA, NASA, SBA), I did not expect anybody else to submit comments. I would appreciate it if you could incorporate these comments and your responses to them into your passback.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:00 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to

Ex. 5 Deliberative Process (DP)

Vlad

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 9/22/2017 1:17:08 PM
To: Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy EOP (PP)]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy EOP (PP)]
CC: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; McLain, Jennifer [McLain.Jennifer@epa.gov]
Subject: RE: EPA Perchlorate Peer Review follow up

Thanks Jim and Vlad. I have schedule the call for 3:00 pm on October 2. You should have the invitation in your in box. I used the distribution list that we had for the last call to identify the invitees.

-----Original Message-----

From: Kim, Jim H. EOP/OMB [mailto: [Ex. 6 Personal Privacy EOP (PP)]]
Sent: Thursday, September 21, 2017 1:56 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy EOP (PP)]; Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; McLain, Jennifer <McLain.Jennifer@epa.gov>
Subject: RE: EPA Perchlorate Peer Review follow up

I can make October 2, but not October 5 at that time.

Jim

-----Original Message-----

From: Dorjets, Vlad EOP/OMB
Sent: Thursday, September 21, 2017 1:38 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; McLain, Jennifer <McLain.Jennifer@epa.gov>; Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy EOP (PP)]
Subject: RE: EPA Perchlorate Peer Review follow up

Eric - Sorry for not replying sooner and thanks for offering to set this up. Unless Jim Kim (who I've copied) has any conflicts, all three times work for me. I realize I'm the one that has been the cause of the delay here but if we can get the invitation to reviewers tomorrow or Monday that would be great so that they will have a week notice to read the report before the call.

-----Original Message-----

From: Burneson, Eric [mailto:Burneson.Eric@epa.gov]
Sent: Tuesday, September 19, 2017 3:27 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy EOP (PP)]
Cc: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; McLain, Jennifer <McLain.Jennifer@epa.gov>
Subject: RE: EPA Perchlorate Peer Review follow up

Vlad:

I wanted to check back with you on potential times for calls with the Federal Agency partners to discuss questions /concerns with the charge. Here are three possible times

October 2, 11:00 to 12:00
October 2, 3:00 - 4:00
October 5: 2:00 - 3:00

Please let me know which of these times works for the critical folks from OMB and I will send out a meeting request to the Federal Partners for that time. Thanks for your continued assistance with this important action.

Eric Burneson, P.E.
Director of Standards and Risk Management Office of Ground Water and Drinking Water U.S. Environmental Protection Agency
202 564 5250

On Sep 13, 2017, at 12:11 PM, Burneson, Eric <Burneson.Eric@epa.govmailto:Burneson.Eric@epa.gov> wrote:
Federal Agency Partners:

Thank you again for your input on the peer review charge for the materials to inform the Safe Drinking Water Act Decision Making on Perchlorate. I am writing to inform you that the following Federal Register announcements are scheduled for publication on Friday, September 15 (and will be available on line for public inspection tomorrow, Sept 14)

1. Federal Register.

Title: Request for Public Comments to be sent to Versar, Inc., on an Interim List of Perchlorate in Drinking Water Expert Peer Reviewers and Draft Peer Review Charge Questions FRL #: 9967-70-OW Docket #: EPA-HQ-OW-2016-0439

1. Federal Register.

Title: Request for Public Comments to be sent to EPA on Peer Review Materials to Inform the Safe Drinking Water Act Decision Making on Perchlorate FRL #: 9967-69-OW Docket #: EPA-HQ-OW-2016-0438

As we stated in our previous discussions, EPA is committed to working with you to assure we have a robust peer review and scientifically sound analysis to inform decision making. We will be scheduling a teleconference during the week of October 2, 2017, to answer any questions you have about the charge and to discuss your preliminary feedback on the charge. We are asking for your feedback on the revised charge questions via email by October 6, 2017.

As we discussed, in order for your comments on the draft report to be considered by the peer reviewers, they will need to be submitted to the docket through the processes identified in the second Federal Register notice above (comment due date will be October 30, 2017). However we will also be open to any input that you wish to provide directly to us via email and can schedule a second teleconference to discuss questions and preliminary comments during the week of October 23 if there is interest.

Thanks again for your continued involvement in this important scientific analysis.

Eric Burneson, P.E.

Director of Standards and Risk Management Office of Ground Water and Drinking Water U.S. Environmental Protection Agency
202 564 5250

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 5/17/2019 2:27:30 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: Perchlorate

Sounds good. I will be in my office at 4:00.

From: Dorjets, Vlad EOP/OMB [mailto: [Ex. 6 Personal Privacy (PP)]]
Sent: Friday, May 17, 2019 10:26 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: Perchlorate

How about 4:00? Happy to just call you then.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Thursday, May 16, 2019 7:48 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: Re: Perchlorate

Absolutely Vlad I have a meeting at 3 but am otherwise available

Sent from my iPhone

On May 16, 2019, at 7:12 PM, Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)] > wrote:

Eric – I just finished my first pass of the two documents. I plan to read them again tomorrow but already have a couple thoughts it may be helpful for me to share tomorrow. Can the two of us chat briefly and informally tomorrow afternoon? I'm free after 2:00.

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 4/29/2019 9:29:32 PM
To: Jones, Lisa M. EOP/OMB Ex. 6 Personal Privacy (PP)
Subject: Accepted: E.O. 12866 MTG re: National Primary Drinking Water Regulations: Regulation of Perchlorate (RIN 2040-AF28)
Location: Room 9258, New Executive Office Building (NEOB)/OMB - 725 17th Street, NW, Washington, DC 20503
Start: 4/30/2019 8:00:00 PM
End: 4/30/2019 8:30:00 PM
Show Time As: Busy

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 4/22/2019 8:35:10 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
CC: Nickerson, William [Nickerson.William@epa.gov]; Huff, Lisa [Huff.Lisa@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]
Subject: RE: Proposed Perchlorate NPDWR
Attachments: PerchlorateOccMonitoringReport 4-22-19.docx

Vlad:

Attached please find an updated Perchlorate Occurrence and Monitoring Document. This document is referenced as an EPA 2018 publication in the draft FRN but it has not yet been published. We have updated this document from the 2018 draft and we will release it when we open the docket for the proposed regulation. We will have to update our references to reflect the fact that it is a 2019 document prior to that time.

Let me know if you have any additional questions or concerns.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Burneson, Eric
Sent: Monday, April 22, 2019 12:22 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**; Christ, Lisa <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Cc: Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Vlad:

Attached please find the Draft Maximum Contaminant Level Goal Technical Support Document that you asked about. Also find attached the slides we plan to present at the inter-agency teleconference call on Thursday. I plan to send you the Occurrence and Monitoring Document by the end of the day today.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: Monday, April 22, 2019 9:21 AM
To: Christ, Lisa <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>; Burneson, Eric

<Burneson.Eric@epa.gov>

Cc: Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>

Subject: RE: Proposed Perchlorate NPDWR

Also, do you expect to be able to send me the draft TSD today? I'd like to send that to reviewers as soon as possible. I'm also interested in seeing whether it includes certain discussion that is absent from the NPRM and HRRCA such as:

Ex. 5 Deliberative Process (DP)

From: Dorjets, Vlad EOP/OMB

Sent: Monday, April 22, 2019 9:18 AM

To: 'Christ, Lisa' <Christ.Lisa@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>

Subject: RE: Proposed Perchlorate NPDWR

Lisa – It looks like there was some miscommunication. Sorry if my message wasn't clear. I already have the draft HRRCA since, as you correctly pointed out, it was submitted together with the draft NPRM for review. The document I'm interested in seeing is the *Perchlorate Occurrence and Monitoring Report*. It is referenced numerous times in the document and is dated 2018 – not 2019 – which leads me to believe it has already been released and is not part of the rulemaking package yet I can't find it online.

From: Christ, Lisa <Christ.Lisa@epa.gov>

Sent: Sunday, April 21, 2019 11:51 AM

To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>

Subject: RE: Proposed Perchlorate NPDWR

Vlad,

The HRRCA has not been publicly released as all of the support documents for the proposal are still draft. We sent the draft HRRCA at the same time the proposal was sent to OMB. I'm attaching it again here with the proposal.

Lisa

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**

Sent: Friday, April 19, 2019 1:37 PM

To: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>

Subject: RE: Proposed Perchlorate NPDWR

Sam – One more request. I'm seeing lots of references in HRRCA to EPA's *Perchlorate Occurrence and Monitoring Report* dated 2018 (so assume it's been released already) but it does not come up in a Google search and is not included among the other key Perchlorate documents on your website. Could you please sent that to me too?

From: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>

Sent: Friday, April 19, 2019 12:58 PM

To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**; Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Huff, Lisa

<Huff.Lisa@epa.gov>

Subject: RE: Proposed Perchlorate NPDWR

Hi Vlad,

I just noticed that I inadvertently provided an earlier version of Volume I which Eric forwarded to you. Attached is a revised version of Volume 1 which incorporates minor editorial changes to the document. Sorry for the inconvenience.

Also, in response to your request I am attaching Volumes 2 and 3 of the Report.

Thanks

Sam

=====

Samuel Hernández Quiñones, P.E.
Environmental Engineer
Office of Water
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
202-564-1735

"USEPA Protecting Human Health and the Environment"

From: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>

Sent: Friday, April 19, 2019 12:01 PM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>

Subject: RE: Proposed Perchlorate NPDWR

Eric/Lisa – Could you please share Volumes II and III?

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Wednesday, April 17, 2019 4:23 PM

To: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>

Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>

Subject: RE: Proposed Perchlorate NPDWR

Vlad:

We can provide the requested support documents. The first document has been shared previously with many of the other Federal Agencies (see my email to Jim Kim on July 11, 2018) but we are happy to share this document again. It is attached to this email. The second document is currently under revision to incorporate some of the modifications we made just prior to submitting the proposed NPDWR. We expect to be able to send this document early next week.

Eric Burneson, P.E.

Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB <[REDACTED]>
Sent: Tuesday, April 16, 2019 3:54 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Eric,

Kevin Bromberg has apparently already skimmed (if not actually read) the NPRM and is requesting two documents referenced in the preamble: the "proposed approaches to inform the derivation of a maximum contaminant level goal for perchlorate in drinking water" (reference 2018d) and the TSD (reference 2018e). Could you please let me know the status of these two documents? In case they're not currently available or will not be available soon it would help me to understand what they documents do and do not contain.

Vlad

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, April 16, 2019 1:10 PM
To: Dorjets, Vlad EOP/OMB <[REDACTED]>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: Proposed Perchlorate NPDWR

Vlad

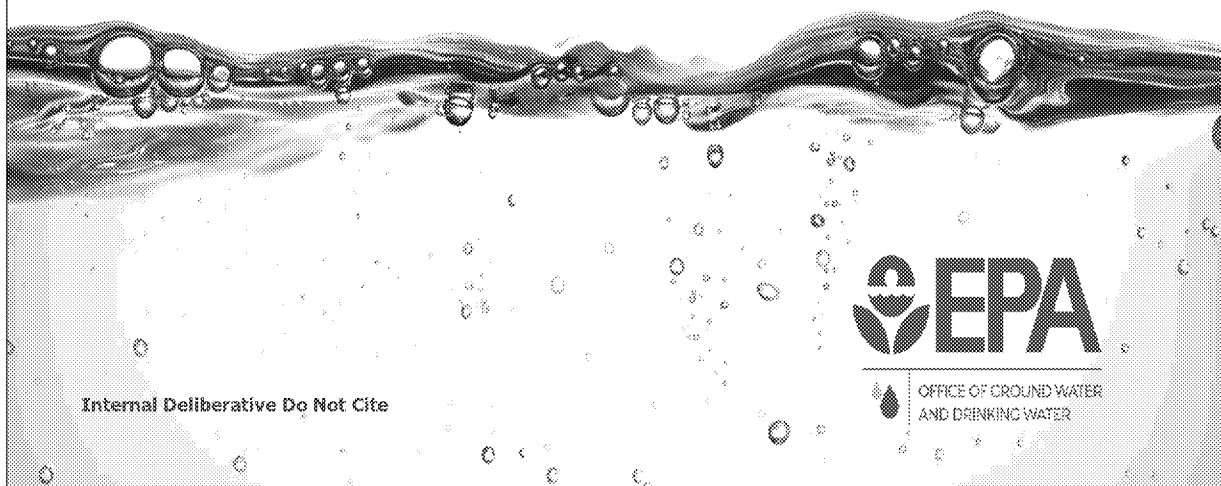
Thanks for touching base regarding the perchlorate proposed drinking water regulation. As we discussed I have blocked time on April 25 at 3:00 pm for a briefing to the other Federal Agency's on the perchlorate proposal. We will send an updated presentation to you early next week for distribution to the other Agency partners. I am assuming this will be a teleconference but let me know if you or other Federal partners would be interested in coming to EPA Offices for the meeting and I can book a larger room for the discussion.

As I mentioned I will be out of the office Thursday and Friday this week but if you have questions about the draft proposal you can contact Lisa Christ in my absence. Lisa's number is 202 564 8354.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

Perchlorate Proposed Rule

April 2019



Regulatory History



- EPA included perchlorate on the 1st, 2nd, and 3rd Candidate Contaminant Lists (CCL); published 1998, 2005 and 2009.
- EPA included perchlorate in the 1st Unregulated Contaminant Monitoring Rule (UCMR1); data submitted 2001-2005.
 - 4.1% of water systems reported measurements greater than 4 µg/L (the minimum reporting level)
- 2008 preliminary Regulatory Determination.
 - Health Reference Level (HRL) of 15 µg/L based on reference dose of 0.7 µg/kg/day (NAS)
 - Decision to not regulate based on low occurrence at 15 µg/L
- 2009 supplemental request for comment on new analysis of derived alternative HRLs for 14 life stages.
 - Life-stage dependent HRLs ranging from 1 to 47 µg/L
- 2011 final Regulatory Determination
 - Decision to regulate based on meaningful opportunity to improve public health protection for 5 -16 million people served water containing perchlorate
 - SDWA required EPA to promulgate a proposed drinking water regulation by February 11, 2013, and a final rule by August 11, 2014.
- 2016 Lawsuit for failure to meet SDWA statutory deadlines for rule promulgation
 - Consent decree requires EPA to propose a drinking water regulation for Perchlorate no later than May 28, 2019, and finalize a rule by December 19, 2019.

Perchlorate Health Effects



- Perchlorate competes with iodide for transport through the sodium-iodide symporter (NIS) into the thyroid gland, which is a necessary step in the production of thyroid hormones Triiodothyronine (T3) and Thyroxine (T4) (NRC).
- Thyroid hormones are essential to the growth and development of fetuses, infants, and young children, as well as to metabolism and energy regulation throughout the lifespan (NRC).
- NRC evaluated the health implications of perchlorate ingestion at the request of EPA and other federal agencies in 2005. The committee concluded that hypothyroidism is the first adverse effect in the mode-of-action model. Any effects downstream of hypothyroidism clearly would be adverse. If perchlorate exposure did result in hypothyroidism, possible outcomes would be metabolic sequelae at any age and abnormal growth and development in fetuses or children (NRC).
- In 2013, EPA received input from SAB who concluded: To integrate the available information to develop a MCLG for perchlorate, the SAB urges the EPA to expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure. Incorporating these components into the model offers the opportunity for much greater scientific rigor in establishing quantitative relationships between perchlorate exposure and adverse effects at sensitive life stages.
- The association of maternal hypothyroxinemia with offspring neurodevelopment is supported by three meta-analyses (including one full systematic review), all of which conclude maternal hypothyroxinemia is associated with increased risk of cognitive delay, intellectual impairment, or lower scores on performance tests when considering the entire body of evidence on this topic (Fan & Wu, 2016; Thompson et al., 2018; Wang et al., 2016).
- The American Thyroid Association also concludes that "overall, available evidence appears to show an association between hypothyroxinemia and cognitive development of the offspring"

EPA Science Advisory Board Recommendations



- In 2012, EPA sought recommendations from the EPA Science Advisory Board (SAB) on how to use the RfD and proposed approach to derive an MCLG. The May 2013 SAB report recommended the following:
 - “derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling (PBPK);”
 - “expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure;”
 - “utilize an MOA framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition to thyroid hormone changes and finally neurodevelopmental impacts;”
 - “extend the [BBDR] model expeditiously to...provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages.”
- To address the SAB recommendations, EPA and FDA scientists worked collaboratively to develop models to predict the effects perchlorate exposure has on thyroid function in pregnant women and their children.

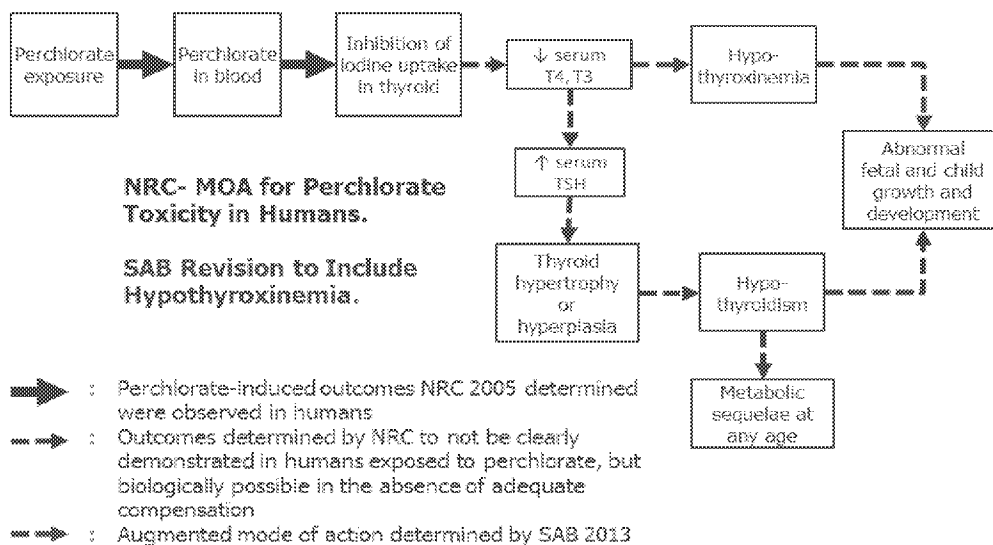
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“extend the [BBDR] model expeditiously to...provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages” (SAB, 2013, p. 19).

The SAB stated that EPA should more directly consider thyroid hormone changes as relevant to sensitive life stages; specifically, fetuses of hypothyroxinemic pregnant women and infants and neonates exposed to perchlorate through either water-based formula preparations or the breast milk of lactating women. This is because thyroid hormone deficiency is known to produce adverse effects on human neurodevelopment, an effect to which the above mentioned sensitive life stages are especially vulnerable. This direction is different from the conclusions of the NRC report, which based the RfD on the non-adverse effect of reduced iodide uptake and suggested examining pregnant women with hypothyroidism or iodide deficiency. The SAB approach focuses on the subtler changes in thyroid hormones (specifically fT4) associated with maternal hypothyroxinemia rather than broader changes in thyroid hormones (both fT4 and TSH) associated with hypothyroidism (Science Advisory Board (SAB), 2013, p. 25). Furthermore, the SAB recommended EPA consider available data on potential adverse health effects (i.e., neurodevelopmental outcomes) due to thyroid hormone level perturbations, regardless of the cause of those perturbations.

Perchlorate Mode of Action



MCLG Development - Overview

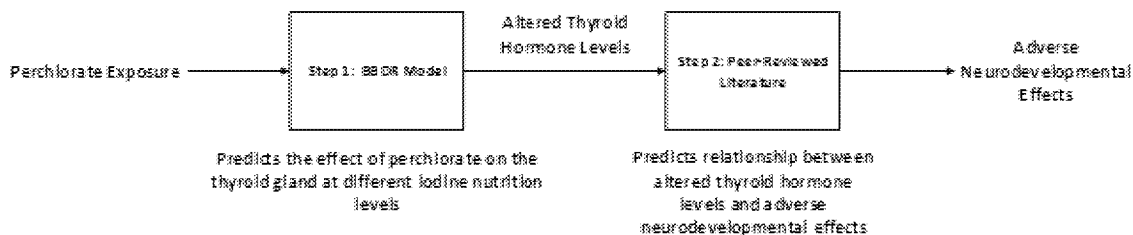


Two Step Analysis and Peer Review:

2017: EPA (with support of FDA) prepared and peer reviewed a BBDR model that predicts thyroid hormone changes that result from iodine nutrition and perchlorate exposure.

2018: EPA prepared and peer reviewed a revised BBDR model and a analysis of epidemiologic studies examining thyroid hormones changes in pregnant women to neurodevelopment effects.

"Overall, the committee agreed that the EPA and its collaborators have prepared a highly innovative state-of-the-science set of quantitative tools to evaluate neurodevelopmental effects that could arise from drinking water exposure to perchlorate. While there is always room for improvement of the models, with limited additional work to address the committee's comments below, the current models are fit-for-purpose to determine an MCLG."



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MCLG Development

Thyroid Hormone Changes and Neurodevelopment Impacts



Studies on Thyroid Hormone Changes and Neurodevelopment :

- Not every paper found a statistically significant association between maternal fT4 as a continuous variable (i.e., 5 of the initially identified 16 studies identified as potentially useful to inform a dose-response function) and the neurodevelopmental outcome of interest.
- However, several meta-analyses Fan & Wu, 2016; Thompson et al., 2018 and Wang et al., 2016, the American Thyroid Association (Alexander et al., 2017) and the U.S. EPA's SAB (2013) have concluded there is a relationship between maternal hypothyroxinemia and various neurodevelopmental outcomes.
- For derivation of the MCLG, EPA selected its reanalysis of the Korevaar study data based on the following factors:
 - 3600 mother-child data pairs,
 - Dose-response function for sensitive population of interest,
 - Able to control for confounders, and
 - Readily interpretable endpoint (IQ).

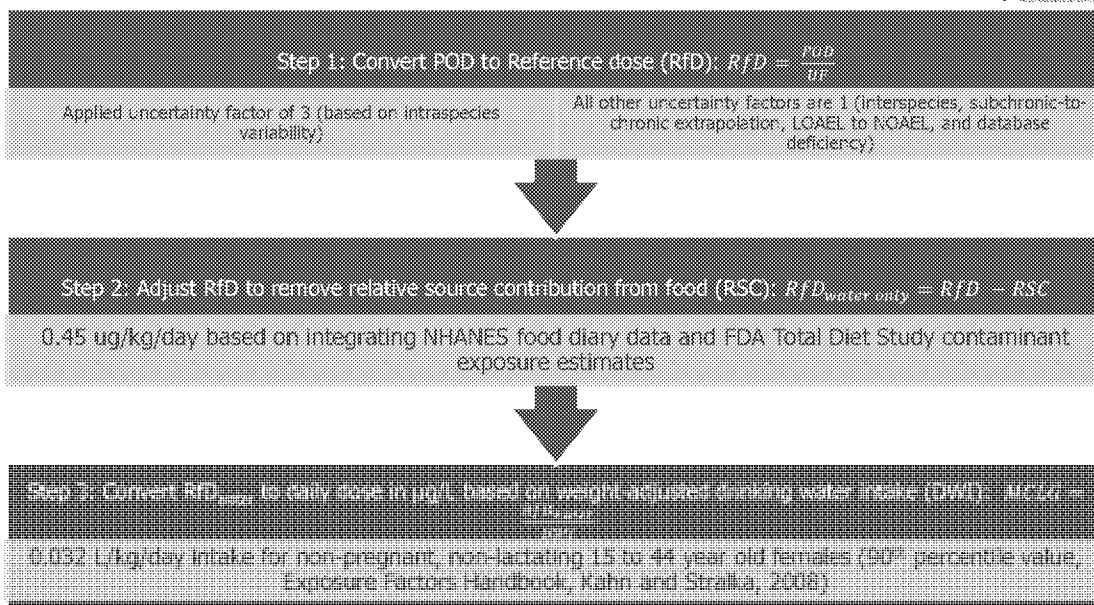
Point of Departure: Dose of perchlorate to result in a thyroid hormone change associated with:

1% change or 1-point IQ decrement (alternative):
POD=3.1
 $\mu\text{g/kg/day}$

2% change or 2-point IQ decrement:
POD=6.7
 $\mu\text{g/kg/day}$

3% change or 3-point IQ decrement (alternative):
POD=10.8
 $\mu\text{g/kg/day}$

POD to MCLG



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MCLG – Calculation

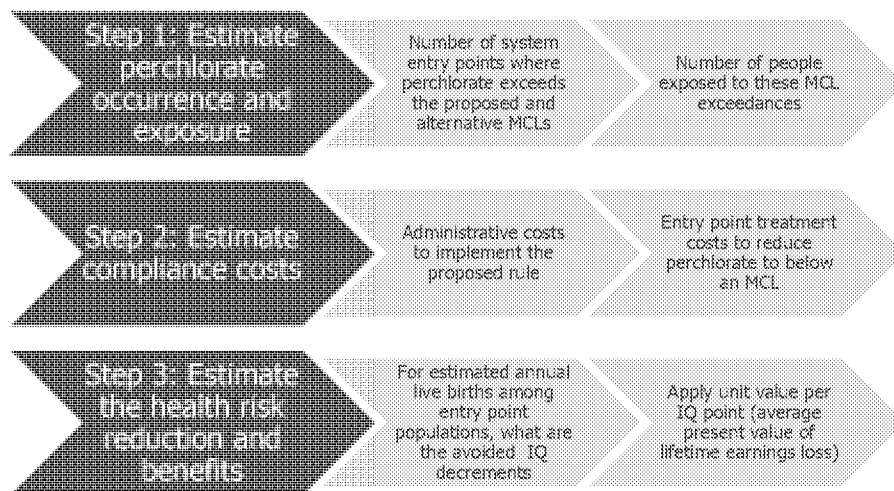


Item	1 IQ point decrement (alternative)	2 IQ point decrement	3 IQ point decrement (alternative)
POD	3.1 µg/kg/day	6.7 µg/kg/day	10.8 µg/kg/day
RfD = POD/UF	1.03 = 3.1/3	2.23 = 6.7/3	3.6 = 10.8/3
MCLG = (RfD-RSC)/DWI	18.13 = (1.03-0.45)/0.032	55.62 = (2.23-0.45)/0.032	90 = (3.6-0.45)/0.032
MCLG (rounded)	18 µg/L	56 µg/L	90 µg/L
Note: the RSC is the perchlorate dose (µg/kg/L) from food, not a percentage allocated to drinking water			

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Ex. 5 Deliberative Process (DP)

Benefit-Cost Analysis Method Overview



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Ex. 5 Deliberative Process (DP)

Cost Estimates



Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

Benefit-Cost Analysis Summary



Ex. 5 Deliberative Process (DP)

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Proposed Rule and Alternatives



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- Ex. 5 Deliberative Process (DP)**

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 5/20/2019 8:15:47 PM
To: Dorjets, Vlad EOP/OMB Ex. 6 Personal Privacy (PP)
Subject: Meeting Forward Notification: EPA Perchlorate MCL NPRM
Start: 5/20/2019 8:30:00 PM
End: 5/20/2019 9:00:00 PM
Show Time As: Busy

Your meeting was forwarded

Burneson, Eric has forwarded your meeting request to additional people.

Meeting

EPA Perchlorate MCL NPRM

Meeting Time

Monday, May 20, 2019 4:00 PM - Monday, May 20, 2019 4:30 PM

Recipients

Messier, Dawn

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 5/16/2019 3:41:39 PM
To: Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Vlad Dorjets
(**Ex. 6 Personal Privacy (PP)**)
Subject: Hold for OMB call re Perchlorate
Location: EPA East 2331 A or (**Ex. 6 Personal Privacy (PP)**) Code (**Ex. 6 Personal Privacy (PP)**)
Start: 5/22/2019 7:00:00 PM
End: 5/22/2019 8:00:00 PM
Show Time As: Tentative

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 4/25/2019 1:47:05 PM
To: Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]
CC: Johnson, Ann [Johnson.Ann@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Vladik_Dorjets@ [Ex. 6 Personal Privacy (PP)]
BCC: DCRoomEast2339/DC-ICC-OW-OGWDW [DCRoomEast2339@epa.gov]
Subject: Inter Agency Briefing on Proposed Perchlorate NPDWR
Attachments: Perchlorate Interagency Brief 4-25-19 V2.pptx
Location: DCRoomEast2339/DC-ICC-OW-OGWDW call in [Ex. 6 Personal Privacy (PP)] passcode [Ex. 6 Personal Privacy (PP)]
Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Tentative

OMB has scheduled an Inter-Agency teleconference at this time for EPA to brief other Federal Agencies on the draft proposed drinking water regulation for perchlorate. EPA will deliver the attached slides and ask for any clarifying questions at the end.

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 5/22/2019 3:54:20 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: Nickerson, William [Nickerson.William@epa.gov]
Subject: RE: Perchlorate Status?

We are very close

From: Dorjets, Vlad EOP/OMB [mailto: [Ex. 6 Personal Privacy (PP)]]
Sent: Wednesday, May 22, 2019 11:54 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: Perchlorate Status?

Any update on perchlorate passback?

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 4/25/2019 1:41:56 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: Call in # for tomorrow
Attachments: Perchlorate Interagency Brief 4-25-19 V2.pptx

Thanks Vlad: if it not too late we corrected a couple of typos in the attached presentation

From: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>
Sent: Wednesday, April 24, 2019 5:30 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: Call in # for tomorrow

Ah, good point. Yeah I provided a call-in number in the invite I sent agencies. Number is [Ex. 6 Personal Privacy (PP)] passcode [Ex. 6 Personal Privacy (PP)]

By the way there seems to be A LOT of interest in this call. As expected, there seems to be a lot of confusion about what you are doing and why. In particular, people are finding it very odd that [Ex. 5 Deliberative Process (DP)]
[Ex. 5 Deliberative Process (DP)] Not sure how explicit you will want to be about that on the call but I'll defer to you. Also, after several requests, I'm going to tell people that I am extending deadline on comments from Monday morning to Monday COB. That means I'll get you everything on Tuesday. Based on several agencies' input, that half day makes a lot of difference for them as they can work on their own comments over the weekend and leave Monday for internal clearance. I'll be at my desk for another hour or so if you want to discuss any of this or the call in general.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Wednesday, April 24, 2019 5:15 PM
To: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>
Subject: Call in # for tomorrow

Vlad:
Apologies if we already decided this, but are we providing the teleconference line tomorrow or are you? I am okay either way but I don't know the number if OMB is providing the teleconference service. If EPA is providing the number, the call in number will [Ex. 6 Personal Privacy (PP)] Code: [Ex. 6 Personal Privacy (PP)] Please let me know either way. Thanks

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 4/25/2019 1:01:25 PM
To: Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]
CC: Johnson, Ann [Johnson.Ann@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Vladik_Dorjets ([Ex. 6 Personal Privacy (PP)])
BCC: DCRoomEast2339/DC-ICC-OW-OGWDW [DCRoomEast2339@epa.gov]
Subject: Inter Agency Briefing on Proposed Perchlorate NPDWR
Attachments: Perchlorate Interagency Brief 4-25-19.pptx
Location: DCRoomEast2339/DC-ICC-OW-OGWDW call in ([Ex. 6 Personal Privacy (PP)]) passcode ([Ex. 6 Personal Privacy (PP)])
Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Tentative

OMB has scheduled an Inter-Agency teleconference at this time for EPA to brief other Federal Agencies on the draft proposed drinking water regulation for perchlorate. EPA will deliver the attached slides and ask for any clarifying questions at the end.

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 5/20/2019 6:19:54 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**

Subject: Accepted: EPA Perchlorate MCL NPRM

Location: Dial-in: **Ex. 6 Personal Privacy (PP)**; Passcode: **Ex. 6 Personal Privacy (PP)**

Start: 5/20/2019 8:00:00 PM

End: 5/20/2019 8:30:00 PM

Show Time As: Busy

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 3/5/2019 10:21:07 PM
To: Vlad Dorjets [Ex. 6 Personal Privacy (PP)]; Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]
BCC: DCRoomEast2418/DC-ICC-OW-OGWDW [DCRoomEast2418DC@epa.gov]
Subject: Perchlorate Proposed NPDWR
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)] Conf ID [Ex. 6 Personal Privacy (PP)]
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Tentative

Pre Brief for OMB on the proposed perchlorate drinking water regulation.

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 5/1/2019 9:51:29 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: Nickerson, William [Nickerson.William@epa.gov]
Subject: RE: OMB Comments on Draft Perchlorate MCL NPRM (1 of 2)

Vlad: We will do what we can to get revised documents back to you quickly. However given the discussion of topics that are of significant interest to OMB and the other federal agency's in both of the documents (i.e., the MCLG derivation and the benefits assessment) I am doubtful we can break the HRRCA free before we have worked through the issues on the NPRM.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Wednesday, May 01, 2019 1:02 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: OMB Comments on Draft Perchlorate MCL NPRM (1 of 2)

Eric – To the extent that you are able to make the necessary revisions to the HRRCA sooner than to the NPRM (which I expect to be the case) I encourage you to send that document back to us and not wait for the whole package. In fact, I would encourage you to do that even if it means putting in some placeholders for items still being worked on in the NPRM.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, April 30, 2019 9:25 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: Re: OMB Comments on Draft Perchlorate MCL NPRM (1 of 2)

Thanks Vlad

Sent from my iPhone

On Apr 30, 2019, at 8:16 PM, Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)] wrote:

Bill,

Please find attached OMB's comments on EPA's draft proposal setting an MCL for perchlorate. Specifically, I have attached comments on the NPRM document and the HRRCA. I have also provide a

Ex. 5 Deliberative Process (DP)

Please note that I am still awaiting comments from one particular agency. I explained the situation to Eric earlier today so he can provide additional context. I'm hoping to get clarity on the situation tomorrow.

Please don't hesitate to let me know if you have any questions about OMB's comments. In fact, once you have had a chance to review them, it may make sense for us to set up a call to get your reactions and answer any questions you may have. Either way, once I receive a revised set of documents from you, I intend to circulate them for a *very quick* interagency review. While I would normally prefer to get another round of staff-level comments before determining which outstanding concerns require elevation, I don't think we will have the luxury of doing that. When I circulate the comments for another round of review, I thus intend to specify agencies only provide substantive comments which have policy-level support.

Vlad

<EPA Perchlorate MCL IQ Valuation (OMB 04-30-19).docx>

<EPA Perchlorate MCL NPRM (OMB 04-30-19).docx>

<EPA Perchlorate MCL HRRCA (OMB 04-30-19).docx>

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 5/23/2019 3:18:50 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: Manibusan, Mary [manibusan.mary@epa.gov]
Subject: RE: Uploaded new versions of Perchlorate, 2040-AF28 into ROCIS

Vlad:

Many thanks to you on your excellent work coordinating the review of this very important action. We appreciate your careful consideration of all the key issues and your balanced approach to resolving them in a way that assures the public can provide informed input. We look forward to working with you on the final action for this contaminant and on other key drinking water regulatory issues.

Per your request pasted below is the draft of the press statement we expect will be going out today.

DRAFT PRESS RELEASE

EPA Seeks Comment on Proposed Options for Regulating Perchlorate in Drinking Water

WASHINGTON – Today, the U.S. Environmental Protection Agency (EPA) released a notice of proposed rulemaking that seeks public input on a range of options regarding the regulation of perchlorate in public drinking water systems.

The agency is seeking comment on a proposed National Primary Drinking Water Regulation (NPDWR) for perchlorate to establish a Maximum Contaminant Level (MCL) and a health-based Maximum Contaminant Level Goal (MCLG) at 56 micrograms per liter.

In addition, the agency is seeking comment on three alternative regulatory options:

- An MCL and MCLG for perchlorate set at 18 micrograms per liter.
- An MCL and MCLG for perchlorate set at 90 micrograms per liter.
- Withdrawal of the agency's 2011 determination to regulate perchlorate in drinking water.

The agency is requesting comment on the proposed rule's perchlorate monitoring and reporting requirements for public water systems and a list of treatment technologies that would enable water systems to comply with the MCL, including affordable compliance technologies for small systems serving 10,000 persons or less.

EPA will accept public comment on the proposal for 60 days after publication in the Federal Register via <http://www.regulations.gov> [Docket ID No. EPA-HQ-OW-2018-0780].

From: Dorjets, Vlad EOP/OMB [mailto: [Ex. 6 Personal Privacy (PP)]]
Sent: Thursday, May 23, 2019 10:58 AM
To: Manibusan, Mary <Manibusan.Mary@epa.gov>; Adams, Darryl <Adams.Darryl@epa.gov>
Cc: Burneson, Eric <Burneson.Eric@epa.gov>; Evalenko, Sandy <Evalenko.Sandy@epa.gov>; Nurse, Leanne <Nurse.Leanne@epa.gov>
Subject: RE: Uploaded new versions of Perchlorate, 2040-AF28 into ROCIS

OMB has concluded its review of the Perchlorate rule. I realize this review had some particular challenges so we want to thank everybody for all their hard work and thoughtful responses to OMB and interagency comments.

We understand that EPA is planning on signing and rolling out this rule later today. We would appreciate it if you could send us your roll-out material in advance so that we can take a quick look to see how EPA is planning on messaging this NPRM.

From: Manibusan, Mary <Manibusan.Mary@epa.gov>

Sent: Thursday, May 23, 2019 10:44 AM

To: Adams, Darryl <Adams.Darryl@epa.gov>

Cc: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP) >}; Burneson, Eric <Burneson.Eric@epa.gov>; Evalenko, Sandy <Evalenko.Sandy@epa.gov>; Nurse, Leanne <Nurse.Leanne@epa.gov>

Subject: Re: Uploaded new versions of Perchlorate, 2040-AF28 into ROCIS

Vlad,
Please confirm when OMB has officially concluded.
Thanks,
Mary

Sent from my iPhone

On May 23, 2019, at 10:41 AM, Adams, Darryl <Adams.Darryl@epa.gov> wrote:

Vlad et al,
I've uploaded the new versions into ROCIS. Please let me if there are any issues. Thank you.

<image003.jpg>

Darryl Adams
Regulatory Management Division
Office of Policy, U.S. EPA
202 564-6569
Mail Code 1803A, Room 3512D WJC North

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 3/29/2019 1:55:29 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: Nickerson, William [Nickerson.William@epa.gov]
Subject: Follow up on perchlorate
Location: call in [Ex. 6 Personal Privacy (PP)] code [Ex. 6 Personal Privacy (PP)]
Start: 3/29/2019 5:00:00 PM
End: 3/29/2019 5:30:00 PM
Show Time As: Tentative

Vlad:
Lets use my call in number above.

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Friday, March 29, 2019 8:51 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: Re: Call tomorrow?

Either time works. Want me to call you at 1?

Sent from my iPhone

On Mar 28, 2019, at 6:26 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:

Vlad:
Do you have time for a call tomorrow between 1 and 2? If not then how about 2:30 or 3:30?

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 4/17/2019 8:23:21 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
CC: Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]
Subject: RE: Proposed Perchlorate NPDWR
Attachments: MCLG Approaches Vol1 Main ReportCLEAN.docx

Vlad:

We can provide the requested support documents. The first document has been shared previously with many of the other Federal Agencies (see my email to Jim Kim on July 11, 2018) but we are happy to share this document again. It is attached to this email. The second document is currently under revision to incorporate some of the modifications we made just prior to submitting the proposed NPDWR. We expect to be able to send this document early next week.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: Tuesday, April 16, 2019 3:54 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: Proposed Perchlorate NPDWR

Eric,

Kevin Bromberg has apparently already skimmed (if not actually read) the NPRM and is requesting two documents referenced in the preamble: the "proposed approaches to inform the derivation of a maximum contaminant level goal for perchlorate in drinking water" (reference 2018d) and the TSD (reference 2018e). Could you please let me know the status of these two documents? In case they're not currently available or will not be available soon it would help me to understand what they documents do and do not contain.

Vlad

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Tuesday, April 16, 2019 1:10 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
Subject: Proposed Perchlorate NPDWR

Vlad

Thanks for touching base regarding the perchlorate proposed drinking water regulation. As we discussed I have blocked time on April 25 at 3:00 pm for a briefing to the other Federal Agency's on the perchlorate proposal. We will send an updated presentation to you early next week for distribution to the other Agency partners. I am assuming this will be a teleconference but let me know if you or other Federal partners would be interested in coming to EPA Offices for the meeting and I can book a larger room for the discussion.

As I mentioned I will be out of the office Thursday and Friday this week but if you have questions about the draft proposal you can contact Lisa Christ in my absence. Lisa's number is 202 564 8354.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 5/17/2019 8:07:13 PM
To: Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Vlad Dorjets

Ex. 6 Personal Privacy (PP)

Subject: Hold for OMB call re Perchlorate
Location: EPA East 2331 A or **Ex. 6 Personal Privacy (PP)** :ode **Ex. 6 Personal Privacy (PP)**
Start: 5/21/2019 7:30:00 PM
End: 5/21/2019 8:30:00 PM
Show Time As: Tentative

Due to some schedule changes I was just informed of regarding signature of this proposal we will need to have our discussion on Tuesday rather than Wednesday. Can we please hold this time for a follow up discussion?

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 5/17/2019 4:15:03 PM
To: Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Vlad Dorjets

Ex. 6 Personal Privacy (PP)

Subject: Hold for OMB call re Perchlorate
Location: EPA East 2331 A or Ex. 6 Personal Privacy (PP) code Ex. 6 Personal Privacy (PP)
Start: 5/21/2019 6:00:00 PM
End: 5/21/2019 7:00:00 PM
Show Time As: Tentative

Due to some schedule changes I was just informed of regarding signature of this proposal we will need to have our discussion on Tuesday rather than Wednesday. Can we please hold this time for a follow up discussion?

Message

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 3/7/2019 9:01:32 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; McLain, Jennifer [McLain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Johnson, Ann [Johnson.Ann@epa.gov]
Subject: RE: Perchlorate Proposed NPDWR

Its Conference ID [Ex. 6 Personal Privacy (PP)]

-----Original Message-----

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Thursday, March 07, 2019 4:00 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>; Khera, Rajiv <Khera.Rajiv@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; McLain, Jennifer <McLain.Jennifer@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Johnson, Ann <Johnson.Ann@epa.gov>
Subject: Re: Perchlorate Proposed NPDWR

We're having trouble dialing in using the conference ID below

Sent from my iPhone

> On Mar 7, 2019, at 3:03 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:
>
> Pre Brief for OMB on the proposed perchlorate drinking water regulation.
>
> <Perchlorate Brief OMB 3-7-19 _v3.pptx> <meeting.ics>

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 3/7/2019 8:59:19 PM
To: Vlad Dorjets [Ex. 6 Personal Privacy (PP)]; Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Johnson, Ann [Johnson.Ann@epa.gov]
BCC: DCRoomEast2418/DC-ICC-OW-OGWDW [DCRoomEast2418DC@epa.gov]
Subject: Perchlorate Proposed NPDWR
Attachments: Perchlorate Brief OMB 3-7-19_v3.pptx
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)] Conf ID [Ex. 6 Personal Privacy (PP)]
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Tentative

Correction to the conference code ID

Pre Brief for OMB on the proposed perchlorate drinking water regulation.

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 3/7/2019 8:02:44 PM
To: Vlad Dorjets [Ex. 6 Personal Privacy (PP)]; Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [hernandez.samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Johnson, Ann [Johnson.Ann@epa.gov]
BCC: DCRoomEast2418/DC-ICC-OW-OGWDW [DCRoomEast2418DC@epa.gov]
Subject: Perchlorate Proposed NPDWR
Attachments: Perchlorate Brief OMB 3-7-19_v3.pptx
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)] Conf ID [Ex. 6 Personal Privacy (PP)]
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Tentative

Pre Brief for OMB on the proposed perchlorate drinking water regulation.

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 7/9/2018 8:56:05 PM
To: James_H_Kim [Ex. 6 Personal Privacy EOP (PP)]
Subject: Meeting Forward Notification: TWG - Perchlorate
Start: 7/9/2018 9:00:00 PM
End: 7/9/2018 9:30:00 PM
Show Time As: Busy

Your meeting was forwarded

Burneson, Eric has forwarded your meeting request to additional people.

Meeting

TWG - Perchlorate

Meeting Time

Wednesday, July 11, 2018 2:00 PM - Wednesday, July 11, 2018 3:00 PM

Recipients

Nickerson, William

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

Appointment

From: Burneson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CACB9A8D49F49AF80531E9E2CCB9018-EBURNESO]
Sent: 7/9/2018 5:27:13 PM
To: James_H_Kim [Ex. 6 Personal Privacy EOP (PP)]
Subject: Accepted: TWG - Perchlorate
Location: Conference Call
Start: 7/11/2018 6:00:00 PM
End: 7/11/2018 7:00:00 PM
Show Time As: Busy

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 3/5/2019 10:21:09 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Vlad Dorjets (Ex. 6 Personal Privacy (PP))
(Ex. 6 Personal Privacy (PP)); Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov];
Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen
[Flaherty.Colleen@epa.gov]; Schwab, Margo EOP/OMB (Ex. 6 Personal Privacy (PP))
Subject: Perchlorate Proposed NPDWR
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in (Ex. 6 Personal Privacy (PP)) Conf ID (Ex. 6 Personal Privacy (PP))
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Busy

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 3/5/2019 10:21:09 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Vlad Dorjets [Ex. 6 Personal Privacy (PP)]; Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]
Subject: Perchlorate Proposed NPDWR
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)] Conf ID [Ex. 6 Personal Privacy (PP)]
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Tentative

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 3/5/2019 10:21:07 PM
To: Vlad Dorjets ([Ex. 6 Personal Privacy (PP)]); Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]
Subject: Perchlorate Proposed NPDWR
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in ([Ex. 6 Personal Privacy (PP)] Conf ID ([Ex. 6 Personal Privacy (PP)])
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Tentative

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 3/7/2019 8:02:44 PM
To: Vlad Dorjets [Ex. 6 Personal Privacy (PP)]; Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Johnson, Ann [Johnson.Ann@epa.gov]
Subject: Perchlorate Proposed NPDWR
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)] Conf ID [Ex. 6 Personal Privacy (PP)]
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Tentative

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 4/16/2019 4:42:13 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]
CC: Johnson, Ann [Johnson.Ann@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Vladik_Dorjets [Ex. 6 Personal Privacy (PP)]
Subject: Hold for Inter Agency Briefing on Proposed Perchlorate NPDWR
Location: DCRoomEast2339/DC-ICC-OW-OGWDW
Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Busy

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 4/16/2019 4:42:13 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]
CC: Johnson, Ann [Johnson.Ann@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Vladik_Dorjetskiy [Ex. 6 Personal Privacy (PP)]
Subject: Inter Agency Briefing on Proposed Perchlorate NPDWR
Location: DCRoomEast2339/DC-ICC-OW-OGWDW call in [Ex. 6 Personal Privacy (PP)], passcode [Ex. 6 Personal Privacy (PP)]
Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Busy

Appointment

Sent: 3/5/2019 5:56:38 PM
To: Christ, Lisa [Christ.Lisa@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [khera.rajiv@epa.gov]; Strong, Jamie [Strong.Jamie@epa.gov]; Vladik_Dorjets([Ex. 6 Personal Privacy (PP)]) Flowers, Lynn [Flowers.Lynn@epa.gov]

Subject: Perchlorate

Start: 3/6/2019 7:00:00 PM
End: 3/6/2019 8:00:00 PM
Show Time As: Busy

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 3/5/2019 10:21:09 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Vlad Dorjets (Ex. 6 Personal Privacy (PP))
(Ex. 6 Personal Privacy (PP)) Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov];
Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen
[Flaherty.Colleen@epa.gov]; Schwab, Margo EOP/OMB (Ex. 6 Personal Privacy (PP)); Johnson, Ann
[Johnson.Ann@epa.gov]
Subject: Perchlorate Proposed NPDWR
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in (Ex. 6 Personal Privacy (PP)) Conf (Ex. 6 Personal Privacy (PP))
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Busy

Appointment

From: Christ, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10DBD8E424704E43B5A50F74A4DAC626-LCHRIST]
Sent: 4/18/2019 2:17:59 PM
To: Vladik_Dorjets; Ex. 6 Personal Privacy (PP)
Subject: FW: Hold for Inter Agency Briefing on Proposed Perchlorate NPDWR
Location: DCRoomEast2339/DC-ICC-OW-OGWDW

Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Tentative

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 6/5/2020 4:07:12 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)] Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]
Subject: EO12866: OMB Comments on Perchlorate Notice
Location: Skype Meeting
Start: 6/5/2020 7:30:00 PM
End: 6/5/2020 8:00:00 PM
Show Time As: Busy

Vlad can we discuss two topics regarding the comments on the perchlorate notice?

: **Ex. 5 Deliberative Process (DP)**

→ [Join Skype Meeting](#)

Trouble Joining? [Try Skype Web App](#)

Join by phone

Toll number: [Ex. 6 Personal Privacy (PP)] access code: [Ex. 6 Personal Privacy (PP)] Dial-in Number) English (United States)

[Find a local number](#)

[Ex. 6 Personal Privacy (PP)] same as access code above)

[Forgot your dial-in PIN?](#) | [Help](#)

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]

Sent: Friday, June 05, 2020 10:07 AM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>;

Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks and that works. Note that I have just gotten off the phone with DOJ regarding whether this notice is [Ex. 5 Deliberative Process (DP)]

Ex. 5 Deliberative Process (DP)

[Ex. 5 Deliberative Process (DP)] am not ready to offer any recommendation on [Ex. 5 Deliberative Process (DP)]

Ex. 5 Deliberative Process (DP)

of course, SBA just issued a public letter in the context of the MSGP pushing back on that approach but I may be able to convince them to [Ex. 5 Deliberative Process (DP)]

[Ex. 5 Deliberative Process (DP)] We can discuss further later today or next week.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Friday, June 5, 2020 9:15 AM

To: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad

We received this additional set of EOP comment and we will fold this in with the OMB, SBA and USDA comments. I assume your deadline for inter agency comments was yesterday and there should be no more comments forthcoming. Regarding this afternoon, I am not certain if we need a conversation at this stage as we are still evaluating the comments, but I would like to put a placeholder on your calendar for 3:30 just in case it is needed. I will follow up later this morning to confirm and let you know what if any topics we want to discuss. Does that work?

From: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>

Sent: Friday, June 05, 2020 8:58 AM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks for combining the comments. Unfortunately, I need to throw another curve ball because I received some late comments from an EOP reviewer that I have to pass on. They are attached. You will find that many are technical/stylistic but there are also a couple legal questions. I would appreciate it if you could incorporate these comments and responses into your master passback as well.

Sorry again for the piecemeal submission of comments. Hopefully, it's not a huge inconvenience for you and, if anything, has saved more time than it has cost.

As for chatting, I may have a little time after the EO meeting but I have an EO meeting on another rule at 3:00. We can play by ear but I'm happy to pencil in a chat at 2:30? Would just be me and you (in which case one of us can just call the other) or a broader group requiring a conference line? If we don't have enough time, I'm completely free after 3:00 meeting so would be happy pick think up at, say, 3:30 or 4:00.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Friday, June 5, 2020 8:33 AM

To: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad: We have combined the three comment documents into a single file and will prepare a passback with this combined file. Are you available after the 12866 meeting with AWWA this afternoon in case we have any questions about the comments?

From: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>

Sent: Thursday, June 04, 2020 6:05 PM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Really sorry but it looks like I jumped the gun more than I had realized; I just received comments from SBA which I wasn't expecting. I'm not sure I agree with all of SBA's comments so, perhaps, once you've reviewed these and other comments we can chat briefly about options. Hopefully these are the last of the comments.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:05 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: 'Parikh, Pooja' <Parikh.Pooja@epa.gov>; 'Christ, Lisa' <Christ.Lisa@epa.gov>; 'Johnson, Ann' <Johnson.Ann@epa.gov>; 'Wehling, Carrie' <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Murphy's Law is alive and well. Just as I clicked send on the message below, I received the attached comments from USDA. Having heard from all the agencies I knew may be interested in perchlorate (DOD, HHS/FDA, NASA, SBA), I did not expect anybody else to submit comments. I would appreciate it if you could incorporate these comments and your responses to them into your passback.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:00 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Vlad

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 3/5/2019 10:21:09 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Vlad Dorjets [Ex. 6 Personal Privacy (PP)]
[Ex. 6 Personal Privacy (PP)]; Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov];
Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen
[Flaherty.Colleen@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)] Johnson, Ann
[Johnson.Ann@epa.gov]
Subject: Perchlorate Proposed NPDWR
Attachments: Perchlorate Brief OMB 3-7-19_v3.pptx
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)] Conf ID [Ex. 6 Personal Privacy (PP)]
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Busy

Correction to the conference code ID

Pre Brief for OMB on the proposed perchlorate drinking water regulation.

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 4/16/2019 4:42:13 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]
CC: Johnson, Ann [Johnson.Ann@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Vladik_Dorjets [Ex. 6 Personal Privacy (PP)]
Subject: Inter Agency Briefing on Proposed Perchlorate NPDWR
Attachments: Perchlorate Interagency Brief 4-25-19 V2.pptx
Location: DCRoomEast2339/DC-ICC-OW-OGWDW call in [Ex. 6 Personal Privacy (PP)] passcode [Ex. 6 Personal Privacy (PP)]
Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Busy

OMB has scheduled an Inter-Agency teleconference at this time for EPA to brief other Federal Agencies on the draft proposed drinking water regulation for perchlorate. EPA will deliver the attached slides and ask for any clarifying questions at the end.

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 3/7/2019 8:59:19 PM
To: Vlad Dorjets [Ex. 6 Personal Privacy (PP)]; Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Johnson, Ann [Johnson.Ann@epa.gov]
Subject: Perchlorate Proposed NPDWR
Attachments: Perchlorate Brief OMB 3-7-19_v3.pptx
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)] Conf ID [Ex. 6 Personal Privacy (PP)]
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Tentative

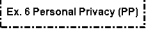
Correction to the conference code ID

Pre Brief for OMB on the proposed perchlorate drinking water regulation.

Appointment

From: Christ, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10DBD8E424704E43B5A50F74A4DAC626-LCHRIST]
Sent: 4/23/2019 8:51:51 PM
To: Jones, Lisa M. EOP/OMB Ex. 6 Personal Privacy (PP)
Subject: Accepted: E.O. 12866 MTG re: National Primary Drinking Water Regulations: Regulation of Perchlorate (RIN 2040-AF28)
Location: Room 9258, New Executive Office Building (NEOB)/OMB - 725 17th Street, NW, Washington, DC 20503
Start: 4/30/2019 8:00:00 PM
End: 4/30/2019 8:30:00 PM
Show Time As: Busy

Appointment

From: Christ, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10DBD8E424704E43B5A50F74A4DAC626-LCHRIST]
Sent: 4/18/2019 2:17:59 PM
To: Vladik_Dorjets@
Subject: FW: Hold for Inter Agency Briefing on Proposed Perchlorate NPDWR
Location: DCRoomEast2339/DC-ICC-OW-OGWDW
Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Tentative

Hi Vlad – We're all set at the new time.
Lisa

-----Original Appointment-----

From: Burneson, Eric
Sent: Tuesday, April 16, 2019 12:42 PM
To: Burneson, Eric; Christ, Lisa; Hernandez-Quinones, Samuel; Khera, Rajiv; Nickerson, William
Cc: Johnson, Ann; Messier, Dawn; Mclain, Jennifer
Subject: Hold for Inter Agency Briefing on Proposed Perchlorate NPDWR
When: Thursday, April 25, 2019 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomEast2339/DC-ICC-OW-OGWDW

OMB is scheduling an Inter Agency teleconference at this time for EPA to brief other Federal Agencies on the draft proposed drinking water regulation for perchlorate. EPA should plan on updating the slide deck we used to brief OMB for this presentation and to answer clarifying questions from Inter Agency reviewers.

Appointment

From: Christ, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10DBD8E424704E43B5A50F74A4DAC626-LCHRIST]
Sent: 6/4/2020 8:00:03 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Subject: Accepted: Call w/ DOJ re Perchlorate
Location: **Ex. 6 Personal Privacy (PP)**
Start: 6/4/2020 8:00:00 PM
End: 6/4/2020 9:00:00 PM
Show Time As: Busy

Appointment

From: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]
Sent: 6/16/2017 2:13:49 PM
To: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]; Hafez, Ahmed [Hafez.Ahmed@epa.gov]; Strong, Jamie [Strong.Jamie@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Grevatt, Peter [Grevatt.Peter@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Olson, Daniel [Olson.Daniel@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Vlad Dorjets [Ex. 6 Personal Privacy (PP)]
CC: Behl, Betsy [Behl.Betsy@epa.gov]; OP ADP Calendar [OP_ADP_Calendar@epa.gov]; Nurse, Leanne [Nurse.Leanne@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Flowers, Lynn [Flowers.Lynn@epa.gov]; Schlosser, Paul [Schlosser.Paul@epa.gov]; Huff, Lisa [Huff.Lisa@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; James_H_Kim@ [Ex. 6 Personal Privacy (PP)]
Subject: Perchlorate Peer Review Briefing with EPA
Attachments: DRAFT MCLG Approach Charge 06-01-17v2.docx; DRAFT Perchlorate OMB PBriefing 06-28-17.pdf
Location: [Ex. 6 Personal Privacy (PP)], access code [Ex. 6 Personal Privacy (PP)] Room 2339 WJCE
Start: 6/29/2017 7:00:00 PM
End: 6/29/2017 8:00:00 PM
Show Time As: Busy

Use conference line [Ex. 6 Personal Privacy (PP)] and access code [Ex. 6 Personal Privacy (PP)]

Message

From: Fotouhi, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FEBAF0D56AAB43F8A9174B18218C1182-FOTOUHI, DA]
Sent: 3/14/2019 11:41:33 PM
To: O'Scannlain, Kevin S. EOP/WHO **Ex. 6 Personal Privacy (PP)**
CC: Leopold, Matt (OGC) [Leopold.Matt@epa.gov]
Subject: Perchlorate
Attachments: EPA DRAFT perchlorate.docx

PRIVILEGED—DELIBERATIVE—DO NOT RELEASE

Kevin:

Per our conversation yesterday, please see the attached. Let me know if you have any questions. Thank you.

Best,

David

David Fotouhi

Principal Deputy General Counsel
Office of General Counsel
U.S. Environmental Protection Agency
Tel: +1 202.564.1976
fotouhi.david@epa.gov

Message

From: O'Scannlain, Kevin S. EOP/WHO [Ex. 6 Personal Privacy (PP)]
Sent: 3/14/2019 11:42:23 PM
To: Fotouhi, David [Fotouhi.David@epa.gov]
CC: Leopold, Matt (OGC) [Leopold.Matt@epa.gov]
Subject: RE: Perchlorate

Thanks, David. Will review and revert if I have any follow up.

From: Fotouhi, David <Fotouhi.David@epa.gov>
Sent: Thursday, March 14, 2019 7:42 PM
To: O'Scannlain, Kevin S. EOP/WHO [Ex. 6 Personal Privacy (PP)]
Cc: Leopold, Matt (OGC) <Leopold.Matt@epa.gov>
Subject: Perchlorate

PRIVILEGED—DELIBERATIVE—DO NOT RELEASE

Kevin:

Per our conversation yesterday, please see the attached. Let me know if you have any questions. Thank you.

Best,

David

David Fotouhi

Principal Deputy General Counsel
Office of General Counsel
U.S. Environmental Protection Agency
Tel: +1 202.564.1976
fotouhi.david@epa.gov

Message

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 8/11/2017 7:41:13 PM
To: James_H_Kim@ [Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Grevatt, Peter [Grevatt.Peter@epa.gov]; McClain, Jennifer [McClain.Jennifer@epa.gov]; Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]; Flowers, Lynn [Flowers.Lynn@epa.gov]
Subject: RE: Perchlorate charge
Attachments: DRAFT MCLG Approach Charge 08-11-17.docx

Vlad and Jim:

Thank you for helping to facilitate a constructive meeting with our Federal partners this week on the perchlorate peer review. We believe that the input we received from you and our Federal partners has helped us to communicate more clearly about our analysis and the critical assumptions, strengths and limitations.

Attached is a revised draft charge that responds to the concerns identified in our discussion on Wednesday. In preparing the attached revisions, we tried to better organize the issues and break down complex charge questions into more direct questions. Prior to distribution to the other Federal Agencies, we ask that you review the attached charge and let us know if you have any suggestions for better addressing the identified concerns.

Our goal is to have input from the other Federal Agencies by Friday, August 18th so that we can move forward with the next steps in conducting the peer review. Therefore we hope to have your feedback by early next week.

Thanks in advance for your continued input.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Burneson, Eric
Sent: Tuesday, August 08, 2017 7:29 PM
To: 'Kim, Jim H. EOP/OMB' [Ex. 6 Personal Privacy (PP)]; Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>
Cc: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Grevatt, Peter <Grevatt.Peter@epa.gov>; McClain, Jennifer <McClain.Jennifer@epa.gov>
Subject: RE: Perchlorate charge

Jim:

Thanks very much for your comments on the draft peer review charge. We have incorporated your input in the revised draft charge document (dated 8-8-17) that will soon be distributed to Inter Agency partners. To assist your understanding in how we incorporated your edits we have also prepared the attached response document for your consideration.

Thanks again for your helpful input.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Monday, August 07, 2017 3:45 PM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>
Cc: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)] Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)] Laity, Jim A. EOP/OMB <[Ex. 6 Personal Privacy (PP)]>
Subject: Perchlorate charge

Hi Caryn, Eric and Lynn,

Thank you for your patience as we worked on this. Attached is a version of the charge with our suggestions in tracked changes. Please let me know if you have any questions.

Best regards,
Jim

James Kim, Ph.D., DABT
Office of Management and Budget
[Ex. 6 Personal Privacy (PP)]

Message

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 8/8/2017 11:27:54 PM
To: James_H_Kim@[Ex. 6 Personal Privacy (PP)]; Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]; Flowers, Lynn [Flowers.Lynn@epa.gov]
CC: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Grevatt, Peter [Grevatt.Peter@epa.gov]; McClain, Jennifer [McClain.Jennifer@epa.gov]
Subject: RE: Perchlorate charge
Attachments: DRAFT MCLG Approach Charge 08-08-17.docx; DRAFT MCLG Approach Charge 08-02-17_OMB_EPAsponses.docx

Jim:

Thanks very much for your comments on the draft peer review charge. We have incorporated your input in the revised draft charge document (dated 8-8-17) that will soon be distributed to Inter Agency partners. To assist your understanding in how we incorporated your edits we have also prepared the attached response document for your consideration.

Thanks again for your helpful input.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Monday, August 07, 2017 3:45 PM
To: Muellerleile, Caryn <Muellerleile.Caryn@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>
Cc: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: Perchlorate charge

Hi Caryn, Eric and Lynn,

Thank you for your patience as we worked on this. Attached is a version of the charge with our suggestions in tracked changes. Please let me know if you have any questions.

Best regards,
Jim

James Kim, Ph.D., DABT
Office of Management and Budget

[Ex. 6 Personal Privacy (PP)]

Message

From: Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 8/8/2017 10:15:52 PM
To: Grevatt, Peter [Grevatt.Peter@epa.gov]
Subject: RE: Follow-up from last week's perchlorate meeting

Peter, sorry just seeing this. I am here until 7 if you want to call now. [Ex. 6 Personal Privacy (PP)]

From: Grevatt, Peter [mailto:Grevatt.Peter@epa.gov]
Sent: Tuesday, August 8, 2017 1:23 PM
To: Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: Follow-up from last week's perchlorate meeting

Hi Jim. Thanks again for your folks' participation in the helpful perchlorate meeting last week. I'd like to see whether we can get a few minutes to touch base this afternoon on your request for providing access to information from the report to inform input on the charge questions by OMB and the interagency group. Please let me know if you can squeeze in 5 minutes sometime later today.

Thanks, P. Grevatt

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 4/25/2019 1:01:25 PM
To: Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]
CC: Johnson, Ann [Johnson.Ann@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Vladik_Dorjets@Ex. 6 Personal Privacy (PP)
Subject: Inter Agency Briefing on Proposed Perchlorate NPDWR
Location: DCRoomEast2339/DC-ICC-OW-OGWDW call in Ex. 6 Personal Privacy (PP) passcode Ex. 6 Personal Privacy (PP)
Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Tentative

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 3/6/2019 3:47:58 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Vlad Dorjets [Ex. 6 Personal Privacy (PP)]; Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Johnson, Ann [Johnson.Ann@epa.gov]
Subject: Fw: Perchlorate Proposed NPDWR
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in [Ex. 6 Personal Privacy (PP)] Conf ID [Ex. 6 Personal Privacy (PP)]
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Tentative

Appointment

From: Martin, Italy M. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 6/1/2020 2:56:26 PM
To: Martin, Italy M. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Johnson, Ann [Johnson.Ann@epa.gov]
Subject: FW: E.O. 12866 Meeting 2040-AF28 - National Primary Drinking Water Regulations: Regulation of Perchlorate
Location: TELCONFERENCE

Start: 6/5/2020 6:00:00 PM
End: 6/5/2020 6:30:00 PM
Show Time As: Busy

Recurrence: (none)

-----Original Appointment-----

From: Martin, Italy M. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Friday, May 29, 2020 12:45 PM
To: Martin, Italy M. EOP/OMB; Dorjets, Vlad EOP/OMB; Kymn, Christine J. EOP/OMB; Schwab, Margo EOP/OMB; Kluever, April N. EOP/OMB; Grossman, Andrea L. EOP/OMB; Varcoe, Andrew R. EOP/WHO; Troutman, Joel D. EOP/WHO; Brooke, Francis J. Jr. EOP/WHO; Malpass, Robert H. EOP/WHO; DL CEQ RegReview; Hickey, Jonathan P. EOP/OVP; Sidler, Matthew R. EOP/OMB; 'Burneson.Eric@epa.gov'; 'Parikh.Pooja@epa.gov'
Subject: E.O. 12866 Meeting 2040-AF28 - National Primary Drinking Water Regulations: Regulation of Perchlorate
When: Friday, June 5, 2020 2:00 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: TELCONFERENCE

This meeting was requested by: **American Water Works Association**

Client Name: **Kevin Morley**

Email: kmorley@awwa.org Phone: [Ex. 6 Personal Privacy (PP)]

Call-in: [Ex. 6 Personal Privacy (PP)] Conference ID: [Ex. 6 Personal Privacy (PP)]

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 5/21/2019 4:09:00 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Vlad Dorjets [Ex. 6 Personal Privacy (PP)]
CC: Johnson, Ann [Johnson.Ann@epa.gov]
Subject: FW: Hold for OMB call re Perchlorate
Location: EPA East 2331 A or [Ex. 6 Personal Privacy (PP)] code [Ex. 6 Personal Privacy (PP)]
Start: 5/21/2019 7:30:00 PM
End: 5/21/2019 8:30:00 PM
Show Time As: Busy

-----Original Appointment-----

From: Burneson, Eric
Sent: Thursday, May 16, 2019 11:42 AM
To: Burneson, Eric; Christ, Lisa; Hernandez-Quinones, Samuel; Khera, Rajiv; Nickerson, William; Vlad Dorjets [Ex. 6 Personal Privacy (PP)]
Subject: Hold for OMB call re Perchlorate
When: Tuesday, May 21, 2019 3:30 PM-4:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: EPA East 2331 A or [Ex. 6 Personal Privacy (PP)] code [Ex. 6 Personal Privacy (PP)]

Due to some schedule changes I was just informed of regarding signature of this proposal we will need to have our discussion on Tuesday rather than Wednesday. Can we please hold this time for a follow up discussion?

Appointment

From: Jones, Lisa M. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 4/25/2019 2:36:17 PM
To: Jones, Lisa M. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Johnson, Ann [Johnson.Ann@epa.gov]; Mancini, Dominic J. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Theroux, Rich P. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Thomas, Amanda L. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Kluever, April N. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Glass, Jacob S. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Falk Curtin, Edna T. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Nickerson, William [Nickerson.William@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]
Subject: FW: E.O. 12866 MTG re: National Primary Drinking Water Regulations: Regulation of Perchlorate (RIN 2040-AF28)
Location: Room 9258, New Executive Office Building (NEOB)/OMB - 725 17th Street, NW, Washington, DC 20503
Start: 4/30/2019 8:00:00 PM
End: 4/30/2019 8:30:00 PM
Show Time As: Busy

-----Original Appointment-----

From: Jones, Lisa M. EOP/OMB <[Ex. 6 Personal Privacy (PP)]>
Sent: Tuesday, April 23, 2019 4:39 PM
To: Jones, Lisa M. EOP/OMB; Mancini, Dominic J. EOP/OMB; Theroux, Rich P. EOP/OMB; Dorjets, Vlad EOP/OMB; Thomas, Amanda L. EOP/OMB; Schwab, Margo EOP/OMB; Kluever, April N. EOP/OMB; Glass, Jacob S. EOP/OMB; Falk Curtin, Edna T. EOP/OMB; Nickerson, William; Burneson, Eric; Christ, Lisa
Subject: E.O. 12866 MTG re: National Primary Drinking Water Regulations: Regulation of Perchlorate (RIN 2040-AF28)
When: Tuesday, April 30, 2019 4:00 PM-4:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Room 9258, New Executive Office Building (NEOB)/OMB - 725 17th Street, NW, Washington, DC 20503

This meeting was requested by the American Water Works Association.

Call-in: [Ex. 6 Personal Privacy (PP)] code [Ex. 6 Personal Privacy (PP)]

Here's the link for security information needed and the link may be shared: [Ex. 6 Personal Privacy (PP)]

Please include name as it shows exactly on driver's license or other government-issued identification to be used. Thank you.

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 3/7/2019 8:59:19 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Vlad Dorjets ([Ex. 6 Personal Privacy (PP)]); Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]; Schwab, Margo EOP/OMB ([Ex. 6 Personal Privacy (PP)]); Johnson, Ann [Johnson.Ann@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]
Subject: Perchlorate Proposed NPDWR
Attachments: Perchlorate Brief OMB 3-7-19_v3.pptx
Location: DCRoomEast2418/DC-ICC-OW-OGWDW or call in ([Ex. 6 Personal Privacy (PP)]) Conf ID ([Ex. 6 Personal Privacy (PP)])
Start: 3/7/2019 9:00:00 PM
End: 3/7/2019 10:00:00 PM
Show Time As: Busy

Correction to the conference code ID

Pre Brief for OMB on the proposed perchlorate drinking water regulation.

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 4/25/2019 1:01:25 PM
To: Christ, Lisa [Christ.Lisa@epa.gov]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]; Nickerson, William [Nickerson.William@epa.gov]
CC: Johnson, Ann [Johnson.Ann@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Vladik_Dorjets@ [Ex. 6 Personal Privacy (PP)]
Subject: Inter Agency Briefing on Proposed Perchlorate NPDWR
Attachments: Perchlorate Interagency Brief 4-25-19.pptx
Location: DCRoomEast2339/DC-ICC-OW-OGWDW call in [Ex. 6 Personal Privacy (PP)] passcode [Ex. 6 Personal Privacy (PP)]
Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 4:00:00 PM
Show Time As: Tentative

OMB has scheduled an Inter-Agency teleconference at this time for EPA to brief other Federal Agencies on the draft proposed drinking water regulation for perchlorate. EPA will deliver the attached slides and ask for any clarifying questions at the end.

Appointment

From: Johnson, Ann [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BF046C29B1604A0E9F712B671C4F3CE5-JOHNSON, ANN]
Sent: 6/2/2020 6:15:54 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Subject: Accepted: Call w/ DOJ re Perchlorate
Location: **Ex. 6 Personal Privacy (PP)**
Start: 6/4/2020 8:00:00 PM
End: 6/4/2020 9:00:00 PM
Show Time As: Busy

Appointment

From: Johnson, Ann [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BF046C29B1604A0E9F712B671C4F3CE5-JOHNSON, ANN]
Sent: 6/1/2020 3:10:22 PM
To: Martin, Italy M. EOP/OMB Ex. 6 Personal Privacy (PP)
Subject: Accepted: FW: E.O. 12866 Meeting 2040-AF28 - National Primary Drinking Water Regulations: Regulation of Perchlorate
Location: TELCONFERENCE
Start: 6/5/2020 6:00:00 PM
End: 6/5/2020 6:30:00 PM
Show Time As: Busy

Message

From: Johnson, Ann [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BF046C29B1604A0E9F712B671C4F3CE5-JOHNSON, ANN]
Sent: 6/1/2020 3:10:08 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: perchlorate

Vlad,

Yes, I am. Thank you.

Ann

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Monday, June 1, 2020 10:56 AM
To: Johnson, Ann <Johnson.Ann@epa.gov>
Subject: AFW: perchlorate

Ann – Are you the OP lead on this review? I actually asked Mark who it was last week but never heard back. If so, I'll forward an invitation to you for an EO meeting with AWWA later this week.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Monday, June 1, 2020 10:50 AM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Cc: Johnson, Ann <Johnson.Ann@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>
Subject: perchlorate

Vlad:

I am forwarding an exchange I just had with FDA regarding perchlorate since I believe it originates from Inter Agency review of the final notice. I replied directly to Henry from FDA because I coordinate periodically with him on issues related to bottled water. If there are any other inquiries I will forward them to you as well. Let me know if you would prefer that I handle inquiries like this differently in the future.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Burneson, Eric
Sent: Monday, June 01, 2020 10:42 AM
To: Kim, Henry <Henry.Kim@fda.hhs.gov>
Cc: Robin, Lauren (Posnick) <Lauren.Robin@fda.hhs.gov>
Subject: RE: Draft final EPA determination not to regulate perchlorate

Henry

I am well and safe and I hope the same is true for you.

Thank you for your question about California and Massachusetts. These two states set drinking water standards for perchlorate before EPA made a decision to regulate perchlorate in 2011. These states established their standards in accordance with their State laws, see

>https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/Perchloratehistory.html<, and

><https://www.mass.gov/lists/perchlorate-background-information-and-standards>< for more information.

Regarding a State's ability to promulgate drinking water standards, the Safe Drinking Water Act does not prohibit a state from promulgating regulations that are more stringent than the National Primary Drinking Water Regulations. I hope this is helpful.

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

From: Kim, Henry <Henry.Kim@fda.hhs.gov>
Sent: Monday, June 01, 2020 9:46 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Robin, Lauren (Posnick) <Lauren.Robin@fda.hhs.gov>
Subject: Draft final EPA determination not to regulate perchlorate

Hello Eric,

Hope you are well and keeping safe!

I am currently reviewing the subject document that was provided to FDA for review and had a question that hopefully you can answer or refer to someone who can.

Currently, Massachusetts and California have established a standard for perchlorate (2 and 6 µg/L, respectively). Can I assume these standards would still be in effect for the two states even though EPA will not establish a NPDWR for perchlorate? More generally, even when EPA decides not to regulate a contaminant in public drinking water under the SDWA, individual states can still do so?

Any assistance you can provide is much appreciated.

Regards,

Henry

Henry Kim, Ph.D.
Division of Plant Products and Beverages
Office of Food Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
henry.kim@fda.hhs.gov

Appointment

From: Johnson, Ann [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BF046C29B1604A0E9F712B671C4F3CE5-JOHNSON, ANN]
Sent: 7/10/2018 7:06:25 PM
To: James_H_Kim [Ex. 6 Personal Privacy EOP (PP)]
Subject: Accepted: FW: TWG - Perchlorate
Location: Conference Call
Start: 7/11/2018 6:00:00 PM
End: 7/11/2018 7:00:00 PM
Show Time As: Busy

Message

From: Clark, Joseph R. EOP/WHO [Ex. 6 Personal Privacy (PP)]
Sent: 5/23/2019 3:32:35 AM
To: Leopold, Matt (OGC) [Leopold.Matt@epa.gov]
Subject: Re: FYI -- Discussion with DOJ re perchlorate proposal

That works.

Best,
Joe

Sent from my iPhone

On May 22, 2019, at 9:08 PM, Leopold, Matt (OGC) <Leopold.Matt@epa.gov> wrote:

Can do it tomorrow at 8 am?

Sent from my iPhone

On May 22, 2019, at 10:31 AM, Clark, Joseph R. EOP/WHO [Ex. 6 Personal Privacy (PP)] wrote:

Yes, that'd be great. Just give me a ring whenever would work best for you.

Best,
Joe

Sent from my iPhone

On May 22, 2019, at 10:14 AM, Leopold, Matt (OGC) <Leopold.Matt@epa.gov> wrote:

I'm slammed until after 6. Can we connect then?

Sent from my iPhone

On May 22, 2019, at 9:44 AM, Clark, Joseph R. EOP/WHO
<[Ex. 6 Personal Privacy (PP)]> wrote:

I have a meeting that will end about 10:30 – would that work for you? Otherwise I can call at your convenience.

Best,
Joe

From: Leopold, Matt (OGC) <Leopold.Matt@epa.gov>
Sent: Wednesday, May 22, 2019 9:27 AM
To: Clark, Joseph R. EOP/WHO
[Ex. 6 Personal Privacy (PP)]
Subject: Re: FYI -- Discussion with DOJ re perchlorate proposal

I'm at the EEOB for the next hour. Would you have time at 10:15?

Sent from my iPhone

On May 21, 2019, at 2:34 PM, Clark, Joseph R.
EOP/WHO <[Ex. 6 Personal Privacy (PP)]> wrote:

Absolutely. Would sometime between
11:30 and 3 pm, or after 4:30, work?

Best,
Joe

From: Leopold, Matt (OGC)
<Leopold.Matt@epa.gov>
Sent: Tuesday, May 21, 2019 2:05 PM
To: Clark, Joseph R. EOP/WHO
<[Ex. 6 Personal Privacy (PP)]>
Subject: Fwd: FYI -- Discussion with DOJ
re perchlorate proposal

Joe, can we catch up about this
tomorrow?

Sent from my iPhone

Begin forwarded message:

From: "Fotouhi, David"
<Fotouhi.David@epa.gov>
Date: May 21, 2019 at
1:59:19 PM EDT
To: "Leopold, Matt
(OGC)"
<Leopold.Matt@epa.gov>
<[Ex. 6 Personal Privacy (PP)]>, "Ross, David P"
<ross.davidp@epa.gov>
, "Bolen, Brittany"
<bolen.brittany@epa.gov>
Subject: Fwd: FYI --
Discussion with DOJ re
perchlorate proposal

Please see below.

Sent from my iPhone

Begin forwarded
message:

From:
"Messie
r,

Dawn"
<Messi
er.Daw
n@epa.
gov>

Date:

May
15,
2019 at
11:39:2
3 AM
EDT

To:

"Fotou
hi,
David"
<Fotou
hi.Davi
d@epa.
gov>,
"Burnes

on,
Eric"
<Burne
son.Eric
@epa.g
ov>

Cc:

"Wehli
ng,
Carrie"
<Wehli
ng.Carri
e@epa.
gov>

Subject

: FYI --
**Discuss
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with
DOJ re
perchlo
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propos
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David
and Eric
– Carrie
and I
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Counsel
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OMB to
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During
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Ex. 5 AC/DP

Ex. 5 AC/DP

Ex. 5 AC/DP

S,

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to OMB

Ex. 5 AC/DP

Ex. 5 AC/DP

Ex. 5 AC/DP

Carrie
feel
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chime
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anythin
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Dawn

Dawn
Messie
r
U.S.E.
P.A.
Office
of
Genera
l
Counse
l
Water
Law
Office
202-
564-
5517

Message

From: Leopold, Matt (OGC) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E5CDF09A3924DADA6D322C6794CC4FA-LEOPOLD, MA]
Sent: 5/22/2019 3:02:19 PM
To: Clark, Joseph R. EOP/WHO <[REDACTED]>
BCC: Mutz, John [mutz.john@epa.gov]
Subject: RE: FYI -- Discussion with DOJ re perchlorate proposal

Okay. Will call at 6:30

Matthew Z. Leopold
General Counsel
U.S. Environmental Protection Agency
(202) 564-8040

From: Clark, Joseph R. EOP/WHO <[REDACTED]>
Sent: Wednesday, May 22, 2019 10:32 AM
To: Leopold, Matt (OGC) <Leopold.Matt@epa.gov>
Subject: Re: FYI -- Discussion with DOJ re perchlorate proposal

Yes, that'd be great. Just give me a ring whenever would work best for you.

Best,
Joe

Sent from my iPhone

On May 22, 2019, at 10:14 AM, Leopold, Matt (OGC) <Leopold.Matt@epa.gov> wrote:

I'm slammed until after 6. Can we connect then?

Sent from my iPhone

On May 22, 2019, at 9:44 AM, Clark, Joseph R. EOP/WHO <[REDACTED]> wrote:

I have a meeting that will end about 10:30 – would that work for you? Otherwise I can call at your convenience.

Best,
Joe

From: Leopold, Matt (OGC) <Leopold.Matt@epa.gov>
Sent: Wednesday, May 22, 2019 9:27 AM
To: Clark, Joseph R. EOP/WHO <[REDACTED]>
Subject: Re: FYI -- Discussion with DOJ re perchlorate proposal

I'm at the EEOB for the next hour. Would you have time at 10:15?

Sent from my iPhone

On May 21, 2019, at 2:34 PM, Clark, Joseph R. EOP/WHO <[REDACTED]> wrote:

Absolutely. Would sometime between 11:30 and 3 pm, or after 4:30, work?

Best,
Joe

From: Leopold, Matt (OGC) <Leopold.Matt@epa.gov>
Sent: Tuesday, May 21, 2019 2:05 PM
To: Clark, Joseph R. EOP/WHO <Ex. 6 Personal Privacy (PP) >
Subject: Fwd: FYI -- Discussion with DOJ re perchlorate proposal

Joe, can we catch up about this tomorrow?

Sent from my iPhone

Begin forwarded message:

From: "Fotouhi, David" <Fotouhi.David@epa.gov>
Date: May 21, 2019 at 1:59:19 PM EDT
To: "Leopold, Matt (OGC)" <Leopold.Matt@epa.gov>, "Ross, David P" <ross.davidp@epa.gov>, "Bolen, Brittany" <bolen.brittany@epa.gov>
Subject: Fwd: FYI -- Discussion with DOJ re perchlorate proposal

Please see below.

Sent from my iPhone

Begin forwarded message:

From: "Messier, Dawn" <Messier.Dawn@epa.gov>
Date: May 15, 2019 at 11:39:23 AM EDT
To: "Fotouhi, David" <Fotouhi.David@epa.gov>, "Burneson, Eric" <Burneson.Eric@epa.gov>
Cc: "Wehling, Carrie" <Wehling.Carrie@epa.gov>
Subject: FYI -- Discussion with DOJ re perchlorate proposal

David and Eric – Carrie and I spoke this morning with staff from ENRD, including reps from the law and policy section, as well as our SDNY attorneys, about the perchlorate proposal. They all had a call yesterday with the White House Counsel's office and OMB to which EPA was not invited. During that call, OMB asked DOJ whether

Ex. 5 AC/AWP/DP

Ex. 5 AC/AWP/DP

As a result of our call, DOJ staff plan to send Jon Brightbill a suggested email to OMB stating that **Ex. 5 AC/AWP/DP**

Ex. 5 AC/AWP/DP

Carrie feel free to chime in if I missed anything.

Dawn

Dawn Messier
U.S.E.P.A.
Office of General Counsel
Water Law Office
202-564-5517

Appointment

From: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]
Sent: 6/16/2017 2:13:47 PM
To: Muellerleile, Caryn [Muellerleile.Caryn@epa.gov]; Hafez, Ahmed [Hafez.Ahmed@epa.gov]; Strong, Jamie [Strong.Jamie@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; Grevatt, Peter [Grevatt.Peter@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Olson, Daniel [Olson.Daniel@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)] Vlad Dorjets [Ex. 6 Personal Privacy (PP)]
CC: Behl, Betsy [Behl.Betsy@epa.gov]; OP ADP Calendar [OP_ADP_Calendar@epa.gov]; Nurse, Leanne [Nurse.Leanne@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Flowers, Lynn [Flowers.Lynn@epa.gov]; Schlosser, Paul [Schlosser.Paul@epa.gov]; Huff, Lisa [Huff.Lisa@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; James_H_Kim [Ex. 6 Personal Privacy (PP)]
Subject: Perchlorate Peer Review Briefing with EPA
Location: [Ex. 6 Personal Privacy (PP)] access code [Ex. 6 Personal Privacy (PP)]
Start: 6/29/2017 7:00:00 PM
End: 6/29/2017 8:00:00 PM
Show Time As: Busy

Use conference line [Ex. 6 Personal Privacy (PP)] and access code [Ex. 6 Personal Privacy (PP)]

Appointment

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/20/2019 6:19:08 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Messier, Dawn [Messier.Dawn@epa.gov]; eric.t.gormsen@usdoj.gov; Oakes, Matthew (ENRD) [Matthew.Oakes@usdoj.gov]; Eric.Hostetler@usdoj.gov; Nickerson, William [Nickerson.William@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]
Subject: FW: EPA Perchlorate MCL NPRM
Location: Dial-in: [Ex. 6 Personal Privacy (PP)] Passcode: [Ex. 6 Personal Privacy (PP)]
Start: 5/20/2019 8:00:00 PM
End: 5/20/2019 8:30:00 PM
Show Time As: Tentative

I could really use your help on this call Can you join

-----Original Appointment-----

From: Dorjets, Vlad EOP/OMB [mailto:[Ex. 6 Personal Privacy (PP)]]
Sent: Monday, May 20, 2019 2:19 PM
To: Dorjets, Vlad EOP/OMB; eric.t.gormsen@usdoj.gov; Oakes, Matthew (ENRD); Eric.Hostetler@usdoj.gov; Nickerson, William; Burneson, Eric; Messier, Dawn
Subject: EPA Perchlorate MCL NPRM
When: Monday, May 20, 2019 4:00 PM-4:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Dial-in: [Ex. 6 Personal Privacy (PP)] Passcode: [Ex. 6 Personal Privacy (PP)]

Appointment

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 5/20/2019 6:19:02 PM
To: eric.t.gormsen@usdoj.gov; Oakes, Matthew (ENRD) [Matthew.Oakes@usdoj.gov]; Eric.Hostetler@usdoj.gov; Nickerson, William [Nickerson.William@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Messier, Dawn [Messier.Dawn@epa.gov]

Subject: EPA Perchlorate MCL NPRM

Location: Dial-in [Ex. 6 Personal Privacy (PP)] Passcode [Ex. 6 Personal Privacy (PP)]

Start: 5/20/2019 8:00:00 PM

End: 5/20/2019 8:30:00 PM

Show Time As: Tentative

Recurrence: (none)

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 6/5/2020 4:07:11 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]; Khera, Rajiv [Khera.Rajiv@epa.gov]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]
Subject: EO12866: OMB Comments on Perchlorate Notice
Location: Skype Meeting
Start: 6/5/2020 7:30:00 PM
End: 6/5/2020 8:00:00 PM
Show Time As: Tentative

Vlad can we discuss two topics regarding the comments on the perchlorate notice?

- The uncertainty about the relationship between perchlorate exposure and neurodevelopmental outcomes and
- The consideration of costs and benefits as confirmatory to the Agency's decision not to regulate perchlorate.

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Join by phone

Toll number: [Ex. 6 Personal Privacy (PP)] access code: [Ex. 6 Personal Privacy (PP)] English (United States)

[Find a local number](#)

Conference ID: [Ex. 6 Personal Privacy (PP)]

[Forgot your dial-in PIN?](#) | [Help](#)

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]

Sent: Friday, June 05, 2020 10:07 AM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>;

Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks and that works. Note that I have just gotten off the phone with DOJ regarding whether [Ex. 5 Deliberative Process (DP)]

[Ex. 5 Deliberative Process (DP)] They are going to look into it and get back to me since that may inform subsequent conversation with SBA. I am not ready to [Ex. 5 Deliberative Process (DP)]

Ex. 5 Deliberative Process (DP)

[Ex. 5 Deliberative Process (DP)] We can discuss further later today or next week.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Friday, June 5, 2020 9:15 AM

To: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad

We received this additional set of EOP comment and we will fold this in with the OMB, SBA and USDA comments. I assume your deadline for inter agency comments was yesterday and there should be no more comments forthcoming. Regarding this afternoon, I am not certain if we need a conversation at this stage as we are still evaluating the comments, but I would like to put a placeholder on your calendar for 3:30 just in case it is needed. I will follow up later this morning to confirm and let you know what if any topics we want to discuss. Does that work?

From: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>

Sent: Friday, June 05, 2020 8:58 AM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Thanks for combining the comments. Unfortunately, I need to throw another curve ball because I received some late comments from an EOP reviewer that I have to pass on. They are attached. You will find that many are technical/stylistic but there are also a couple legal questions. I would appreciate it if you could incorporate these comments and responses into your master passback as well.

Sorry again for the piecemeal submission of comments. Hopefully, it's not a huge inconvenience for you and, if anything, has saved more time than it has cost.

As for chatting, I may have a little time after the EO meeting but I have an EO meeting on another rule at 3:00. We can play by ear but I'm happy to pencil in a chat at 2:30? Would just be me and you (in which case one of us can just call the other) or a broader group requiring a conference line? If we don't have enough time, I'm completely free after 3:00 meeting so would be happy pick think up at, say, 3:30 or 4:00.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Friday, June 5, 2020 8:33 AM

To: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Vlad: We have combined the three comment documents into a single file and will prepare a passback with this combined file. Are you available after the 12866 meeting with AWWA this afternoon in case we have any questions about the comments?

From: Dorjets, Vlad EOP/OMB <[REDACTED] Ex. 6 Personal Privacy (PP)>

Sent: Thursday, June 04, 2020 6:05 PM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Really sorry but it looks like I jumped the gun more than I had realized; I just received comments from SBA which I wasn't expecting. I'm not sure I agree with all of SBA's comments so, perhaps, once you've reviewed these and other comments we can chat briefly about options. Hopefully these are the last of the comments.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:05 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: 'Parikh, Pooja' <Parikh.Pooja@epa.gov>; 'Christ, Lisa' <Christ.Lisa@epa.gov>; 'Johnson, Ann' <Johnson.Ann@epa.gov>; 'Wehling, Carrie' <Wehling.Carrie@epa.gov>

Subject: RE: EO12866: OMB Comments on Perchlorate Notice

Murphy's Law is alive and well. Just as I clicked send on the message below, I received the attached comments from USDA. Having heard from all the agencies I knew may be interested in perchlorate (DOD, HHS/FDA, NASA, SBA), I did not expect anybody else to submit comments. I would appreciate it if you could incorporate these comments and your responses to them into your passback.

From: Dorjets, Vlad EOP/OMB

Sent: Thursday, June 4, 2020 5:00 PM

To: 'Burneson, Eric' <Burneson.Eric@epa.gov>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Johnson, Ann <Johnson.Ann@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>

Subject: EO12866: OMB Comments on Perchlorate Notice

Eric,

As promised, attached please find OMB's comments on the perchlorate notice. Please don't hesitate to let me know if you have any questions. Especially, if you have any questions / concerns about how to characterize the role that cost benefit analysis played in the Administrator's decision in light of this afternoon's call. I'm sure you can guess where my office would stand on the matter.

Vlad

Appointment

From: Parikh, Pooja [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5572FACE2E61429CB6F14C3864554CCA-PARIKH, POOJA]
Sent: 6/3/2020 9:03:09 AM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Subject: Accepted: Call w/ DOJ re Perchlorate
Location: **Ex. 6 Personal Privacy (PP)**
Start: 6/4/2020 8:00:00 PM
End: 6/4/2020 9:00:00 PM
Show Time As: Busy

Appointment

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: 6/4/2020 12:36:17 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Wehling, Carrie [Wehling.Carrie@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]
Subject: Call w/ DOJ re Perchlorate
Location: [Ex. 6 Personal Privacy (PP)]
Start: 6/4/2020 8:00:00 PM
End: 6/4/2020 9:00:00 PM
Show Time As: Busy

-----Original Appointment-----

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Tuesday, June 02, 2020 2:14 PM
To: Dorjets, Vlad EOP/OMB; Burneson, Eric; Parikh, Pooja; Christ, Lisa; Johnson, Ann
Subject: Call w/ DOJ re Perchlorate
When: Thursday, June 04, 2020 4:00 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: [Ex. 6 Personal Privacy (PP)]

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 6/1/2020 2:49:39 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
CC: Parikh, Pooja [Parikh.Pooja@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Johnson, Ann [Johnson.Ann@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]
Subject: Perchlorate
Location: Skype Meeting
Start: 6/1/2020 5:00:00 PM
End: 6/1/2020 6:00:00 PM
Show Time As: Busy

-----Original Appointment-----

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Thursday, May 28, 2020 5:36 PM
To: Burneson, Eric; Dorjets, Vlad EOP/OMB
Cc: Parikh, Pooja; Christ, Lisa
Subject: Perchlorate
When: Monday, June 01, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Skype Meeting

Join Skype Meeting

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Toll number: + [Ex. 6 Personal Privacy (PP)] (Dial-in Number) English (United States)

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Conference ID: [Ex. 6 Personal Privacy (PP)]

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From: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>
Sent: Thursday, May 28, 2020 12:26 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>
Subject: RE: Perchlorate

Let's go with 1:00 if that works for you and thanks for setting this up. And to be clear, this is just an informal chat to understand the thinking behind some of the decisions in the document. I don't plan to provide any comments at that time but simply ask a few questions to help inform my thinking as I prepare comments.

From: Burneson, Eric <Burneson.Eric@epa.gov>

Sent: Thursday, May 28, 2020 12:22 PM

To: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>

Cc: Parikh, Pooja <Parikh.Pooja@epa.gov>

Subject: RE: Perchlorate

Vlad; I agree that it would be helpful to discuss the legal considerations involved in this action (including the timeline for clearing the action NLT June 17). I have checked with our General Counsel's Office representative and she is available at either 11am or 1 pm on Monday. Please let me know if you have a preference for either time and I can set up a meeting.
Eric

From: Dorjets, Vlad EOP/OMB <[Ex. 6 Personal Privacy (PP)]>

Sent: Thursday, May 28, 2020 11:42 AM

To: Burneson, Eric <Burneson.Eric@epa.gov>

Subject: Perchlorate

I imagine that a lot of what was drafted in the perchlorate rule is a result of very deliberate legal consideration. I think it would help me to understand whether: [Ex. 5 Deliberative Process (DP)]

[Ex. 5 Deliberative Process (DP)] I expect to be done reading the document tomorrow (too many other things going on that prevent me from reading it straight through) so perhaps we could chat sometime on Monday?

Appointment

From: Wehling, Carrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3e55f11fdc7489698be69849b301da6-CWEHLING]
Sent: 6/4/2020 12:38:27 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Subject: Accepted: Call w/ DOJ re Perchlorate
Location: **Ex. 6 Personal Privacy (PP)**
Start: 6/4/2020 8:00:00 PM
End: 6/4/2020 9:00:00 PM
Show Time As: Busy

Appointment

From: Nickerson, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=148F2C1C05B54F358E29C59B841664AA-WNICKER]
Sent: 3/11/2019 5:23:53 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**

Subject: Accepted: Perchlorate
Location: Dial-in **Ex. 6 Personal Privacy (PP)** **Passcode:** **Ex. 6 Personal Privacy (PP)**

Start: 3/11/2019 8:00:00 PM
End: 3/11/2019 8:30:00 PM
Show Time As: Busy

Appointment

From: Burneson, Eric [Burneson.Eric@epa.gov]
Sent: 3/29/2019 1:55:30 PM
To: Burneson, Eric [Burneson.Eric@epa.gov]; Dorjets, Vlad EOP/OMB Ex. 6 Personal Privacy (PP)
CC: Nickerson, William [Nickerson.William@epa.gov]

Subject: Follow up on perchlorate
Location: call in 866 299 3188 code 202 564 5250

Start: 3/29/2019 5:00:00 PM
End: 3/29/2019 5:30:00 PM
Show Time As: Busy

Vlad:
Lets use my call in number above.

From: Dorjets, Vlad EOP/OMB <Ex. 6 Personal Privacy (PP)>
Sent: Friday, March 29, 2019 8:51 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: Re: Call tomorrow?

Either time works. Want me to call you at 1?

Sent from my iPhone

On Mar 28, 2019, at 6:26 PM, Burneson, Eric <Burneson.Eric@epa.gov> wrote:

Vlad:
Do you have time for a call tomorrow between 1 and 2? If not then how about 2:30 or 3:30?

Eric Burneson, P.E.
Director of Standards and Risk Management
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
202 564 5250

Message

From: Nickerson, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=148F2C1C05B54F358E29C59B841664AA-WNICKER]
Sent: 3/1/2019 3:41:56 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: AWWA Meeting Request

Will do.

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Thursday, February 28, 2019 4:55 PM
To: Nickerson, William <Nickerson.William@epa.gov>
Subject: FW: AWWA Meeting Request

Bill – As I'm sure you know, this will be a very complicated rule and the first MCL EPA has proposed in a while. I thus think we're going to need as much time for the review as we can get. Given the fact that there's a court order on the back end, I would appreciate whatever you can do so that the rule comes in as soon as possible.

From: Burneson, Eric <Burneson.Eric@epa.gov>
Sent: Thursday, February 28, 2019 4:26 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]>
Cc: Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: AWWA Meeting Request

Thanks Vlad: We are very much aware of the Clewell paper and evaluating its assessment of the modeling work we have done. Our plan is to move the package to OMB by the end of next week. Of course that requires a number of things to go right. I have copied Bill on my reply to keep him in the loop.

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Thursday, February 28, 2019 4:06 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: FW: AWWA Meeting Request

Eric,

Hope you're doing well. So you know, we have turned down this meeting request and asked them to contact us when the rule is under review. I'm sure you're all over this paper but wanted to forward it to you anyway. Speaking of which, I assume you're pretty close to submitting this rule. Do you have a sense of when that will be? Note that my colleague Chad is currently having his weekly check-in with OP and I asked him to ask Bill the same thing.

Vlad

From: Kevin Morley <KMorley@awwa.org>
Sent: Thursday, February 28, 2019 3:14 PM
To: Theroux, Rich P. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]; Echols, Mabel E. EOP/OMB [Ex. 6 Personal Privacy (PP)]

Cc: Steve Via <SVia@awwa.org>; Tracy Mehan <tmehan@awwa.org>

Subject: [EXTERNAL] AWWA Meeting Request

Mr. Theroux:

The American Water Works Association would like to meet with you and OIRA staff regarding recent findings related to EPA's Biologically Based Dose Response (BBDR) model for perchlorate (see attached).

We would like to meet with you on Friday, March 8 or Monday, March 11 if that is possible.

Thank you for your time and attention.

Kevin M. Morley, PhD

American Water Works Association
Manager, Federal Relations
1300 Eye Street, NW Suite 701W
Washington, DC 20005
D: 202-326-6124

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American Water Works Association
Dedicated to the World's Most Important Resource ®

Message

From: Nickerson, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=148F2C1C05B54F358E29C59B841664AA-WNICKER]
Sent: 4/12/2019 7:31:38 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: FYI I just got perchlorate

Yes, EA will come at the same time.

I'd prefer to conclude by Friday May 24 if possible; the consent decree date is Tuesday the 28th. Concluding and signing the same day as a consent decree is never pleasant.

Interagency briefing the week of the 22nd sounds right, and I suspect a lot of people would be out next week anyway.

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Friday, April 12, 2019 3:27 PM
To: Nickerson, William <Nickerson.William@epa.gov>
Subject: Re: FYI I just got perchlorate

Fantastic! I'm off today but will distribute first thing Monday morning. Three things in meantime: did you upload EA too? If not when will it be ready? Second, by when do you need me to conclude review to allow you time to meet consent decree? I'm assuming you just have to sign (and perhaps post) the NPRM and not publish in FR, right? Finally, given abridged review time I think we'll need an interagency briefing so that people can ask questions. Thinking two weeks out to leave people enough time to read rule and then use briefing to inform comments.

Sent from my iPhone

On Apr 12, 2019, at 3:20 PM, Nickerson, William <Nickerson.William@epa.gov> wrote:

Upload today is officially possible

Message

From: Nickerson, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=148F2C1C05B54F358E29C59B841664AA-WNICKER]
Sent: 4/11/2019 8:07:04 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Subject: Re: Public Comment Period on a Washington WQS Action?

It's been one of those days

Sent from my iPhone

On Apr 11, 2019, at 3:13 PM, Dorjets, Vlad EOP/OMB <**Ex. 6 Personal Privacy (PP)**> wrote:

Tomorrow is Friday. ;-)

From: Nickerson, William <Nickerson.William@epa.gov>
Sent: Thursday, April 11, 2019 3:07 PM
To: Dorjets, Vlad EOP/OMB <**Ex. 6 Personal Privacy (PP)**>
Subject: Re: Public Comment Period on a Washington WQS Action?

Tomorrow or Friday if everything goes well

Sent from my iPhone

On Apr 11, 2019, at 2:58 PM, Dorjets, Vlad EOP/OMB <**Ex. 6 Personal Privacy (PP)**> wrote:

Thanks. Also, do you have an ETA on perchlorate?

From: Nickerson, William <Nickerson.William@epa.gov>
Sent: Thursday, April 11, 2019 2:47 PM
To: Dorjets, Vlad EOP/OMB <**Ex. 6 Personal Privacy (PP)**>
Subject: RE: Public Comment Period on a Washington WQS Action?

Haven't heard of this; let me check around

From: Dorjets, Vlad EOP/OMB <**Ex. 6 Personal Privacy (PP)**>
Sent: Thursday, April 11, 2019 2:42 PM
To: Nickerson, William <Nickerson.William@epa.gov>
Subject: Public Comment Period on a Washington WQS Action?

Bill – Could you please give me some context on the InsideEPA article below?
Unfortunately, the link to the document they reference is broken so I cannot look into it myself. I know that EPA is considering **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) In case you don't know, that 2016 action has

Washington Decries EPA Plan To Reverse Toxics Water Quality Rule

April 10, 2019

Washington state officials are decrying the Trump administration's plan to reverse an Obama-era rule for the state that set stringent water quality limits for nearly 200 pollutants to protect high levels of fish consumption among Native American communities, saying EPA failed to consult with the state and tribes before announcing the change.

"I'm shocked EPA did not engage with Washington before moving to change the clean water rule. This is a blatant violation of the principles of cooperative federalism and states' rights," Department of Ecology Director Maia Bellon said in an April 10 statement. "I am also very concerned EPA failed to consult with Washington's federally recognized tribes, disregarding federal trust and treaty obligations."

EPA quietly opened a 30-day public comment period April 8 on a proposal to reverse a 2016 decision that led to the water toxics rule, after agreeing last year to grant a 2017 industry petition to reconsider the rule.

Bellon urged EPA water chief David Ross last August to forgo the reversal, acknowledging that while the state initially preferred a different approach to water quality standards for toxics, it decided to embrace the Obama EPA's approach.

"I am writing to clearly state that I oppose changing course now, more than a year and a half after the current standards took effect," Bellon said in an Aug. 7 letter. What the state's communities and businesses need is predictability, certainty and flexibility to meet clean water requirements, and changing course will not provide that, she said.

"Your decision to reconsider the current standards only sets us back and is already causing confusion and unpredictability. It gives no guarantee that the long-term outcome will move us toward cleaner water or provide the certainty that communities and businesses need."

EPA's 2016 water toxics rule, which updated the state's fish consumption rate (FCR) from 6.5 grams per day (g/day) to 175 g/day and maintained a current cancer risk calculation of 10^{-6} , was controversial, with Republican lawmakers arguing that EPA's proposed criteria were too restrictive and that the agency was attempting to overhaul what should be a state regulatory process.

The National Association of Clean Water Agencies, which represents municipal wastewater treatment plants, raised concerns about EPA's role in shaping state standards while industries like Boeing, one of the state's largest employers, said the 175 g/day FCR was unjustified.

Other industry groups also opposed the approach, and the Utility Water Act Group (UWAG) that represents the power sector on water issues petitioned EPA in February 2017 to either repeal or withdraw its 2016 rule.

EPA in the final 2016 rule approved some of the human health water quality criteria that Washington proposed but also disapproved other elements of the state rule and added additional federal standards. "The combination of the EPA-approved criteria from the state's rule and the criteria in the EPA's final federal rule set an appropriate level of protection for all Washington citizens, including tribal members with treaty-protected fishing rights," the agency said at the time. In an Aug. 3 letter to UWAG, Ross said that after reviewing the petition, EPA had decided to reconsider its previous actions. "The Agency intends to move forward with its reconsideration as expeditiously as possible. At the conclusion of the Agency's reconsideration, we will provide a response to your petition setting forth our decisions whether to grant or deny the specific requests in the petition," Ross wrote.

Should EPA decide to conduct a rulemaking to amend any part of the federal rule, the agency would provide an opportunity for notice and comment.

The agency in a March 20 memorandum said it would request public comment starting April 8 on its proposal to reverse the 2016 decision, which will be posted to its regulations.gov portal for agency actions. "If the EPA ultimately reverses its disapproval action and approves any or all of the currently disapproved human health criteria, the Agency would propose to withdraw those criteria from the federal rule . . . in a subsequent rulemaking process with a separate notice and comment period," the memorandum says. -- *Lara Beaven* (lbeaven@iwpnews.com)

Related News | Water |

219586

Appointment

From: Nickerson, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=148F2C1C05B54F358E29C59B841664AA-WNICKER]
Sent: 7/10/2018 3:11:05 PM
To: James_H_Kim [Ex. 6 Personal Privacy EOP (PP)]
Subject: Accepted: FW: TWG - Perchlorate
Location: Conference Call
Start: 7/11/2018 6:00:00 PM
End: 7/11/2018 7:00:00 PM
Show Time As: Busy

Message

From: Nickerson, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=148F2C1C05B54F358E29C59B841664AA-WNICKER]
Sent: 4/1/2019 3:25:24 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Subject: RE: Perchlorate

I'm free until 1, and from 2-3

From: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Sent: Monday, April 01, 2019 10:16 AM
To: Nickerson, William <Nickerson.William@epa.gov>
Subject: Perchlorate

Bill – Do you have a moment at some point to discuss next steps on perchlorate?

Appointment

From: Nickerson, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=148F2C1C05B54F358E29C59B841664AA-WNICKER]
Sent: 4/25/2019 2:36:16 PM
To: Jones, Lisa M. EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: Meeting Forward Notification: E.O. 12866 MTG re: National Primary Drinking Water Regulations: Regulation of Perchlorate (RIN 2040-AF28)
Start: 4/25/2019 3:00:00 PM
End: 4/25/2019 3:30:00 PM
Show Time As: Busy

Your meeting was forwarded

Nickerson, William has forwarded your meeting request to additional people.

Meeting

E.O. 12866 MTG re: National Primary Drinking Water Regulations: Regulation of Perchlorate (RIN 2040-AF28)

Meeting Time

Tuesday, April 30, 2019 4:00 PM - Tuesday, April 30, 2019 4:30 PM

Recipients

Johnson, Ann

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

Appointment

From: Nickerson, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=148F2C1C05B54F358E29C59B841664AA-WNICKER]
Sent: 4/23/2019 9:41:28 PM
To: Jones, Lisa M. EOP/OMB Ex. 6 Personal Privacy (PP)
Subject: Accepted: E.O. 12866 MTG re: National Primary Drinking Water Regulations: Regulation of Perchlorate (RIN 2040-AF28)
Location: Room 9258, New Executive Office Building (NEOB)/OMB - 725 17th Street, NW, Washington, DC 20503
Start: 4/30/2019 8:00:00 PM
End: 4/30/2019 8:30:00 PM

Recurrence: (none)

Appointment

From: Nickerson, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=148F2C1C05B54F358E29C59B841664AA-WNICKER]
Sent: 3/11/2019 5:23:53 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: Accepted: Perchlorate
Location: Dial-in [Ex. 6 Personal Privacy (PP)] Passcode [Ex. 6 Personal Privacy (PP)]
Start: 3/11/2019 8:00:00 PM
End: 3/11/2019 8:30:00 PM
Show Time As: Busy

Appointment

From: Nickerson, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=148F2C1C05B54F358E29C59B841664AA-WNICKER]
Sent: 5/20/2019 7:27:26 PM
To: Dorjets, Vlad EOP/OMB **Ex. 6 Personal Privacy (PP)**
Subject: Accepted: EPA Perchlorate MCL NPRM
Location: Dial-in **Ex. 6 Personal Privacy (PP)** Passcode: **Ex. 6 Personal Privacy (PP)**
Start: 5/20/2019 8:00:00 PM
End: 5/20/2019 8:30:00 PM

Recurrence: (none)

Message

From: Nickerson, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=148F2C1C05B54F358E29C59B841664AA-WNICKER]
Sent: 4/16/2019 2:11:18 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: RE: perchlorate now coming Monday morning

It is in ROCIS now. Was uploaded this morning. I won't bore you with why.

Can you work out the briefing time with Eric Burneson and his shop and just invite me to the meeting. If I can't make it, I can have someone cover the meeting, but Eric and his team are critical to the effort.

From: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Sent: Tuesday, April 16, 2019 10:08 AM
To: Nickerson, William <Nickerson.William@epa.gov>
Subject: RE: perchlorate now coming Monday morning

Bill –No idea what Brittany told Rosario but he was surprised to hear that the rule did not come in yesterday. I really need the rule to come in as soon as possible so that I can get it out to reviewers and begin my own review. Could you please confirm that it will come in today? Also, in the interest of time, when I send it out to reviewers I want to go ahead and schedule a briefing for Thursday the 25th. I am available all day except for 1-3. Could you please let me know if there is a preferred time on your end?

From: Nickerson, William <Nickerson.William@epa.gov>
Sent: Friday, April 12, 2019 5:06 PM
To: Dorjets, Vlad EOP/OMB [Ex. 6 Personal Privacy (PP)]
Subject: perchlorate now coming Monday morning

Appointment

From: O'Neill, Sandra [ONEill.Sandra@epa.gov]
Sent: 3/17/2017 8:33:26 PM
To: O'Neill, Sandra [ONEill.Sandra@epa.gov]; Fuller, Demson [Fuller.Demson@epa.gov]; Kyprianou, Rose [Kyprianou.Rose@epa.gov]; Gayoso, Jose [Gayoso.Jose@epa.gov]; Parsons, Laura [Parsons.Laura@epa.gov]; Weiss, Steven [Weiss.Steven@epa.gov]; Hsieh, Diana [Hsieh.Diana@epa.gov]; Leighton, Timothy [Leighton.Timothy@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Regli, Stig [Regli.Stig@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]; Townsend, Clifton [Townsend.Clifton@epa.gov]
CC: Henson, Wanda [Henson.Wanda@epa.gov]; Wang, Lili [Wang.Lili@epa.gov]
Subject: Pre-meet: OPP/CI Chlorate and Perchlorate Follow-up Discussion
Attachments: 2017 CI Comment Letter on Perchlorate.pdf; PDF Perchlorate Isotope Study.pdf; Agenda for OPP-CI Chlorate-Perchlorate Follow-Up Meeting 3-23-17.docx
Location: DCRoomPYS8100/Potomac-Yard-One
Start: 3/20/2017 6:00:00 PM
End: 3/20/2017 7:00:00 PM
Show Time As: Busy

<!--[if lte mso 15 || CheckWebRef]-->

O'Neill, Sandra has shared a OneDrive for Business file with you. To view it, click the link below.

 Hypochlorite Best Management Practices 3-17-17.docx

<!--[endif]-->

Call in: Ex. 6 Personal Privacy (PP) if in the office or 1-855-Ex. 6 Personal Privacy (PP) if outside the office

Conference Extension: Ex. 6 Personal Privacy (PP)

Participant Code: Ex. 6 Personal Privacy (PP)

Hypochlorites team,

Since our 1-24-17 meeting with the Chlorine Institute (CI), CI has submitted comments on chlorate and perchlorate that may have an impact on our path forward. We've also identified best management practices from OW, AWWA, and the Chlorine Institute. Our next meeting with CI is on Thursday, 3-23-17.

By the end of this meeting, we want to:

- 1.) Review comments from CI
- 2.) Review the BMPs comparison document, are there any BMPs we wouldn't consider?
- 3.) Finalize agenda for 3-23-17 meeting

Please see the following documents:

- 1.) CI Comment Documents
 - a. CI Comment Letter on Perchlorate: reaffirms that AWWA reports predate 1-1-13 implementation of NSF/ANSI Standard 60 and don't reflect perchlorate minimization improvements, perchlorate levels are likely more from naturally occurring chlorate, and a 2016 isotope study (also attached) provides compelling evidence that natural perchlorate is the dominant source of human exposure.
 - b. 2017 CI Comment Letter on NRDC Recommendations: CI negates use of pH as a BMP, and various other non-BMP related issues.
- 2.) Hypochlorite Best Management Practices 3-17-17: compares BMPs from AWWA, CI, and OW.

3.) Agenda for OPP-CI Chlorate-Perchlorate Follow-Up Meeting 3-23-17 (they will be calling in), this agenda is a draft.

Thank you all!

Message

From: Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]
Sent: 5/6/2020 2:49:34 PM
To: Christ, Lisa [Christ.Lisa@epa.gov]
Subject: FW: Request for review - Draft Perchlorate Rule Proposal
Attachments: Version-Control Perchlorate Rule FRN 2-4-19.3_OCSPD.DOCX

Thanks

Sam

=====

Samuel Hernández Quiñones, P.E.
Environmental Engineer
Office of Water
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
202-564-1735

"USEPA Protecting Human Health and the Environment"

From: Miller, Wynne <Miller.Wynne@epa.gov>
Sent: Tuesday, February 19, 2019 8:49 AM
To: Christ, Lisa <Christ.Lisa@epa.gov>; Raffaele, Kathleen <raffaele.kathleen@epa.gov>; Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>
Cc: Kyprianou, Rose <Kyprianou.Rose@epa.gov>
Subject: RE: Request for review - Draft Perchlorate Rule Proposal

Hi Lisa and Sam,

Apologies for missing the Friday deadline but attached are OCSPD's comments on the proposed rule (including comments from the AA's office). In addition, we had a few minor comments on the support documents (see below). Thank you for the opportunity to review.

Best regards,
Wynne and Rose

Support documents included the following attachments:

Attachment 1: This is the main document (82 pages) on the derivation of the MCLG.

Attachment 2: This is the Cost/Benefit analysis (98 pages)

Attachment 3: Perchlorate Occurrence & Monitoring Report (52 pages)

Attachment 4: Costs for treating perchlorate contaminated waters

Attachment 5: Best available treatment technologies

Attachment 6: "Proposed Approaches to Inform the Derivation of a MCLG for Perchlorate in DW"

- OPP had no comments on Attachments 2, 4, 5, and 6.
- On attachment 1 (Technical Support Document for Derivation of the MCLG), we had the following comments:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

- Attachment 3 (Occurrence and Monitoring Document) – Minor typos...

Ex. 5 Deliberative Process (DP)

From: Christ, Lisa

Sent: Monday, February 04, 2019 12:05 PM

To: Kyprianou, Rose <Kyprianou.Rose@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>; Raffaele, Kathleen <raffaele.kathleen@epa.gov>

Cc: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>

Subject: FW: Request for review - Draft Perchlorate Rule Proposal

Just making sure you received the draft.

Thanks-

Lisa

From: Hernandez-Quinones, Samuel

Sent: Monday, February 04, 2019 10:32 AM

To: Johnson, Ann <Johnson.Ann@epa.gov>; Dockins, Chris <Dockins.Chris@epa.gov>; Shao, Nicole <Shao.Nicole@epa.gov>; Miller, Gregory <Miller.Gregory@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>; Foster, Stiven <Foster.Stiven@epa.gov>

Cc: Christ, Lisa <Christ.Lisa@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Flaharty, Stephanie <Flaharty.Stephanie@epa.gov>; Messier, Dawn <Messier.Dawn@epa.gov>; Wehling, Carrie <Wehling.Carrie@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Khera, Rajiv <Khera.Rajiv@epa.gov>

Subject: Request for review - Draft Perchlorate Rule Proposal

Preliminary draft for internal EPA review

Hi,

Attached for your review is the Draft Perchlorate Rule Proposal (Preamble and Regulatory Text). As discussed previously we are asking that you provide your questions and or comments on the draft document to me by COB 2/15/2019. In order to keep with the consent decree deadline, we need to complete this step of the process within two weeks, if there are any issues that require technical discussions please let me know so that we can arrange any necessary working meeting.

I will follow-up with another email later today that contains the draft version of the technical support documents that were used as the basis for the Perchlorate proposal. Since those are very lengthy documents we are not requesting that you submit input and/or comments on those within the two- week time frame.

Please let me know if you have any questions.

Thanks

Sam

=====

Samuel Hernández Quiñones, P.E.
Environmental Engineer
Office of Water
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
202-564-1735

"USEPA Protecting Human Health and the Environment"

Message

From: Wang, Lili [Wang.Lili@epa.gov]
Sent: 2/26/2018 2:41:31 PM
To: Regli, Stig [Regli.Stig@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]
CC: Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]
Subject: FW: Hypochlorites - Interim Decision - Draft
Attachments: Sodium Calcium Potassium Hypochlorites Interim Decision lw.docx

Hi Stig,

I reviewed the OPP document - focusing on the residual chlorine and label language. Attached contains my edits and comments. Can you please take a look and add your edits?

Lisa,

There is some text on perchlorate (e.g., p. 17, 25). You may want to take a look. Feel free to add any edits to the attached file. I'll combine Stig's and your edits and send them to OPP by COB **Wednesday, February 28th**.

Let me know if you have any questions. Thanks,

Lili

From: Bailey, Jessica
Sent: Thursday, February 22, 2018 2:30 PM
To: Wang, Lili <Wang.Lili@epa.gov>
Cc: Fehir, Richard <Fehir.Richard@epa.gov>; Gayoso, Jose <Gayoso.Jose@epa.gov>
Subject: Hypochlorites - Interim Decision - Draft

Good afternoon Lili,

I hope all is well. OPP-AD is in the final stages of drafting the Interim Decision for the Sodium, Calcium, and Potassium Hypochlorites registration review case. Please see attached for our latest draft. We are looking for any input that OW may have as I begin the routing process to OPP-AD management. I will need any edits from you and your team by COB **Wednesday, February 28th**.

Thanks again for all your help and I look forward to hearing from you. Please do share the document with any interested person in OW.

Jessica Bailey

Chemical Review Manager
U.S. Environmental Protection Agency
Office: (703) 347-0148

Office of Pesticide Programs
Antimicrobials Division
Regulatory Management Branch II
Location: PYS-8213

Message

From: Townsend, Clifton [Townsend.Clifton@epa.gov]
Sent: 6/29/2017 6:27:35 PM
To: Christ, Lisa [Christ.Lisa@epa.gov]
Subject: RE: Sodium, Calcium, Potassium Hypochlorite - Preliminary Interim Decision - language for chlorate / perchlorate formation

Hi Lisa,

I am ok with it now. The point you raise does allow us that flexibility in which I am sure we will need. Thanks for clarifying this for me.

Clifton

From: Christ, Lisa
Sent: Thursday, June 29, 2017 1:38 PM
To: Townsend, Clifton <Townsend.Clifton@epa.gov>
Subject: RE: Sodium, Calcium, Potassium Hypochlorite - Preliminary Interim Decision - language for chlorate / perchlorate formation

Hey Clifton,

I understand your point. Combined with the sentence about initiating a NPDWR it is intended to allow us some flexibility in the future and was recommended by OGC.

Let me know if you still have concerns.

Lisa

From: Townsend, Clifton
Sent: Thursday, June 29, 2017 1:04 PM
To: Christ, Lisa <Christ.Lisa@epa.gov>
Subject: RE: Sodium, Calcium, Potassium Hypochlorite - Preliminary Interim Decision - language for chlorate / perchlorate formation

Hi Lisa,

It just seems that when we say that "to inform the Agency's SDWA decision making" that we are presuming that we may reverse the decision to regulate before we have all the information we need to make that conclusion.

Clif

From: Christ, Lisa
Sent: Thursday, June 29, 2017 12:27 PM
To: Townsend, Clifton <Townsend.Clifton@epa.gov>
Subject: RE: Sodium, Calcium, Potassium Hypochlorite - Preliminary Interim Decision - language for chlorate / perchlorate formation

Hi Clif,

What about the highlighted phrases concerns you?
Lisa

From: Townsend, Clifton
Sent: Tuesday, June 27, 2017 10:09 AM
To: Christ, Lisa <Christ.Lisa@epa.gov>
Subject: FW: Sodium, Calcium, Potassium Hypochlorite - Preliminary Interim Decision - language for chlorate / perchlorate formation

Hi Lisa,

Hope all is well. Are you ok with the language below regarding perchlorate? I have a little reservation about the wording that is highlighted.

Clifton

Further, EPA's Office of Water has begun the National Primary Drinking Water Regulation (NPDWR) process for perchlorate. To inform this effort, EPA and Food and Drug Administration scientists are drafting a Biologically Based Dose Response (also known as a Physiologically-Based Pharmacokinetic (PBPK)) model to inform the Agency's Safe Drinking Water Act (SDWA) decision making. In light of this, the Office of Pesticide Programs (OPP) will continue to work with the Office of Water on perchlorate issues during registration review of the hypochlorites.

From: Bailey, Jessica
Sent: Tuesday, June 27, 2017 10:04 AM
To: Christ, Lisa <Christ.Lisa@epa.gov>; Townsend, Clifton <Townsend.Clifton@epa.gov>
Cc: Kyprianou, Rose <Kyprianou.Rose@epa.gov>; Gayoso, Jose <Gayoso.Jose@epa.gov>; Fehir, Richard <Fehir.Richard@epa.gov>
Subject: Sodium, Calcium, Potassium Hypochlorite - Preliminary Interim Decision - language for chlorate / perchlorate formation

Good morning Lisa and Clifton,

As you know from our meetings over the past several weeks, OPP-AD is writing the Preliminary Interim Decision for the Hypochlorites Case (Sodium, Calcium, Potassium). Our document will be finalized this Friday, June 30. Below is a section of the document where we discuss possible chlorate and perchlorate formation in stored hypochlorite solutions. The language has been taken from a response letter that OPP-AD had written to NRDC in January 2017 (attached). I was hoping to run this language by you, to be sure it is satisfactory from the Office of Water's standpoint. Of particular interest in the highlighted text.

1. Possible Chlorate and Perchlorate Formation in Stored Hypochlorite Solutions

On July 31, 2014, the National Resource Defense Council (NRDC) wrote a letter to the Agency concerning observations on tolerances for sodium hypochlorite and calcium hypochlorite to minimize degeneration to perchlorate. While the letter fell outside of any currently open registration review comment period for the hypochlorites, EPA did post NRDC's comment letter, along with a formal response letter, to docket EPA-HQ-OPP-2012-0004 at www.regulations.gov.

EPA concurred with the observation in NRDC's letter that research by the American Water Works Association (AWWA) and the Water Research Foundation suggest the potential for perchlorate to form in stored hypochlorite solutions. As noted in the research, AWWA and the Water Research Foundation found hypochlorite concentration, pH, ionic strength, and temperature were major factors impacting perchlorate, and also importantly, chlorate formation in stored hypochlorite solutions at drinking water utilities. Additionally, recent monitoring data included in the EPA Office of Water's Unregulated Contaminant Monitoring Rule (UCMR 3) found increased levels of chlorate in finished drinking water.^[1]

There have been reported improvements in industry practices to minimize chlorate and perchlorate formation in stored hypochlorite solutions for drinking water, such as the January 2013 implementation of maximum levels of perchlorate and the January 2015 implementation of maximum levels of chlorate per the National Sanitation Foundation (NSF) / American National Standards Institute (ANSI) Standard 60: Drinking Water Treatment Chemicals.^[2]

Further, EPA's Office of Water has begun the National Primary Drinking Water Regulation (NPDWR) process for perchlorate. To inform this effort, EPA and Food and Drug Administration scientists are drafting a Biologically Based Dose Response (also known as a Physiologically-Based Pharmacokinetic (PBPK)) model to inform the Agency's Safe Drinking Water Act (SDWA) decision making. In light of this, the Office of Pesticide Programs (OPP) will continue to work with the Office of Water on perchlorate issues during registration review of the hypochlorites.

Thank you so much and I look forward to hearing from you,

Jessica Bailey

Chemical Review Manager

U.S. Environmental Protection Agency

Office: (703) 347-0148

Office of Pesticide Programs

Antimicrobials Division

Regulatory Management Branch II

Location: PYS-8213

^[1] "EPA Response to NRDC-Observations on Tolerances for Hypochlorite to Minimize Degeneration to Perchlorate, Correspondence" available at <https://www.regulations.gov/docIdBrower?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=SR&D=EPA-HQ-OPP-2012-0004>

^[2] "Chlorine Institute Comment Letter Sodium Hypochlorite Industry Compliance"

Message

From: Bailey, Jessica [bailey.jessica@epa.gov]
Sent: 6/27/2017 2:15:52 PM
To: Christ, Lisa [Christ.Lisa@epa.gov]
Subject: RE: Sodium, Calcium, Potassium Hypochlorite - Preliminary Interim Decision - language for chlorate / perchlorate formation

Thank you Lisa!

From: Christ, Lisa
Sent: Tuesday, June 27, 2017 10:11 AM
To: Bailey, Jessica <bailey.jessica@epa.gov>
Cc: Townsend, Clifton <Townsend.Clifton@epa.gov>; Kyprianou, Rose <Kyprianou.Rose@epa.gov>; Gayoso, Jose <Gayoso.Jose@epa.gov>; Fehir, Richard <Fehir.Richard@epa.gov>; Albert, Ryan <Albert.Ryan@epa.gov>; Rodgers-Jenkins, Crystal <Rodgers-Jenkins.Crystal@epa.gov>
Subject: Re: Sodium, Calcium, Potassium Hypochlorite - Preliminary Interim Decision - language for chlorate / perchlorate formation

Hi Jessica.

Clifton is on detail but I will coordinate with our other branch on reviewing the below.

Sent from my iPhone

On Jun 27, 2017, at 10:04 AM, Bailey, Jessica <bailey.jessica@epa.gov> wrote:

Good morning Lisa and Clifton,

As you know from our meetings over the past several weeks, OPP-AD is writing the Preliminary Interim Decision for the Hypochlorites Case (Sodium, Calcium, Potassium). Our document will be finalized this Friday, June 30. Below is a section of the document where we discuss possible chlorate and perchlorate formation in stored hypochlorite solutions. The language has been taken from a response letter that OPP-AD had written to NRDC in January 2017 (attached). I was hoping to run this language by you, to be sure it is satisfactory from the Office of Water's standpoint. Of particular interest in the highlighted text.

1. Possible Chlorate and Perchlorate Formation in Stored Hypochlorite Solutions

On July 31, 2014, the National Resource Defense Council (NRDC) wrote a letter to the Agency concerning observations on tolerances for sodium hypochlorite and calcium hypochlorite to minimize degeneration to perchlorate. While the letter fell outside of any currently open registration review comment period for the hypochlorites, EPA did post NRDC's comment letter, along with a formal response letter, to docket EPA-HQ-OPP-2012-0004 at www.regulations.gov.

EPA concurred with the observation in NRDC's letter that research by the American Water Works Association (AWWA) and the Water Research Foundation suggest the potential for perchlorate to form in stored hypochlorite solutions. As noted in the research, AWWA and the Water Research Foundation found hypochlorite concentration, pH, ionic strength, and temperature were major factors impacting perchlorate, and also importantly, chlorate formation in stored hypochlorite solutions at drinking water

utilities. Additionally, recent monitoring data included in the EPA Office of Water's Unregulated Contaminant Monitoring Rule (UCMR 3) found increased levels of chlorate in finished drinking water.^[1]

There have been reported improvements in industry practices to minimize chlorate and perchlorate formation in stored hypochlorite solutions for drinking water, such as the January 2013 implementation of maximum levels of perchlorate and the January 2015 implementation of maximum levels of chlorate per the National Sanitation Foundation (NSF) / American National Standards Institute (ANSI) Standard 60: Drinking Water Treatment Chemicals.^[2]

Further, EPA's Office of Water has begun the National Primary Drinking Water Regulation (NPDWR) process for perchlorate. To inform this effort, EPA and Food and Drug Administration scientists are drafting a Biologically Based Dose Response (also known as a Physiologically-Based Pharmacokinetic (PBPK)) model to inform the Agency's Safe Drinking Water Act (SDWA) decision making. In light of this, the Office of Pesticide Programs (OPP) will continue to work with the Office of Water on perchlorate issues during registration review of the hypochlorites.

Thank you so much and I look forward to hearing from you,

Jessica Bailey

Chemical Review Manager
U.S. Environmental Protection Agency
Office: (703) 347-0148

Office of Pesticide Programs
Antimicrobials Division
Regulatory Management Branch II
Location: PYS-8213

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<response to NRDC.pdf>

^[1] "EPA Response to NRDC-Observations on Tolerances for Hypochlorite to Minimize Degeneration to Perchlorate, Correspondence" available at <https://www.regulations.gov/docId/Browser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=SR&D=EPA-HQ-OPP-2012-0004>

^[2] "Chlorine Institute Comment Letter Sodium Hypochlorite Industry Compliance"

From: Bailey, Jessica [bailey.jessica@epa.gov]
Sent: 6/27/2017 2:03:58 PM
To: Christ, Lisa [Christ.Lisa@epa.gov]; Townsend, Clifton [Townsend.Clifton@epa.gov]
CC: Kyprianou, Rose [Kyprianou.Rose@epa.gov]; Gayoso, Jose [Gayoso.Jose@epa.gov]; Fehir, Richard [Fehir.Richard@epa.gov]
Subject: Sodium, Calcium, Potassium Hypochlorite - Preliminary Interim Decision - language for chlorate / perchlorate formation
Attachments: response to NRDC.pdf

Good morning Lisa and Clifton,

As you know from our meetings over the past several weeks, OPP-AD is writing the Preliminary Interim Decision for the Hypochlorites Case (Sodium, Calcium, Potassium). Our document will be finalized this Friday, June 30. Below is a section of the document where we discuss possible chlorate and perchlorate formation in stored hypochlorite solutions. The language has been taken from a response letter that OPP-AD had written to NRDC in January 2017 (attached). I was hoping to run this language by you, to be sure it is satisfactory from the Office of Water's standpoint. Of particular interest in the highlighted text.

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^[2] "Chlorine Institute Comment Letter Sodium Hypochlorite Industry Compliance"

Thank you so much and I look forward to hearing from you,

Jessica Bailey

Chemical Review Manager
U.S. Environmental Protection Agency
Office: (703) 347-0148

Office of Pesticide Programs
Antimicrobials Division
Regulatory Management Branch II
Location: PYS-8213

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Appointment

From: Christ, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10DBD8E424704E43B5A50F74A4DAC626-LCHRIST]
Sent: 3/20/2017 2:21:57 PM
To: Townsend, Clifton [Townsend.Clifton@epa.gov]
Subject: FW: Pre-meet: OPP/CI Chlorate and Perchlorate Follow-up Discussion
Attachments: 2017 CI Comment Letter on Perchlorate.pdf; PDF Perchlorate Isotope Study.pdf; Agenda for OPP-CI Chlorate-Perchlorate Follow-Up Meeting 3-23-17.docx
Location: DCRoomPYS8100/Potomac-Yard-One
Start: 3/20/2017 6:00:00 PM
End: 3/20/2017 7:00:00 PM
Show Time As: Tentative

<!--[if lte mso 15 || CheckWebRef]-->

Christ, Lisa has shared a OneDrive for Business file with you. To view it, click the link below.

 Hypochlorite Best Management Practices 3-17-17.docx

<!--[endif]-->

-----Original Appointment-----

From: O'Neill, Sandra
Sent: Friday, March 17, 2017 4:33 PM
To: O'Neill, Sandra; Fuller, Demson; Kyprianou, Rose; Gayoso, Jose; Parsons, Laura; Weiss, Steven; Hsieh, Diana; Leighton, Timothy; Rodgers-Jenkins, Crystal; Regli, Stig; Christ, Lisa
Cc: Henson, Wanda; Chen, Jimmy; Tricas, Marisa; Wang, Lili
Subject: Pre-meet: OPP/CI Chlorate and Perchlorate Follow-up Discussion
When: Monday, March 20, 2017 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomPYS8100/Potomac-Yard-One

Call in: Ex. 6 Personal Privacy (PP) if in the office or Ex. 6 Personal Privacy (PP) if outside the office

Conference Extension: Ex. 6 Personal Privacy (PP)

Participant Code: Ex. 6 Personal Privacy (PP)

Hypochlorites team,

Since our 1-24-17 meeting with the Chlorine Institute (CI), CI has submitted comments on chlorate and perchlorate that may have an impact on our path forward. We've also identified best management practices from OW, AWWA, and the Chlorine Institute. Our next meeting with CI is on Thursday, 3-23-17.

By the end of this meeting, we want to:

- 1.) Review comments from CI
- 2.) Review the BMPs comparison document, are there any BMPs we wouldn't consider?
- 3.) Finalize agenda for 3-23-17 meeting

Please see the following documents:

- 1.) CI Comment Documents
 - a. CI Comment Letter on Perchlorate: reaffirms that AWWA reports predate 1-1-13 implementation of NSF/ANSI Standard 60 and don't reflect perchlorate minimization improvements, perchlorate levels are likely more from naturally occurring chlorate, and a 2016 isotope study (also attached) provides compelling evidence that natural perchlorate is the dominant source of human exposure.
 - b. 2017 CI Comment Letter on NRDC Recommendations: CI negates use of pH as a BMP, and various other non-BMP related issues.
- 2.) Hypochlorite Best Management Practices 3-17-17: compares BMPs from AWWA, CI, and OW.
- 3.) Agenda for OPP-CI Chlorate-Perchlorate Follow-Up Meeting 3-23-17 (they will be calling in), this agenda is a draft.

Thank you all!

Message

From: Hernandez-Quinones, Samuel [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C46D56B82F143DF82F81D322BD109D7-HERNANDEZ-QUINONES, SAMUEL]
Sent: 6/13/2019 3:44:03 PM
To: Silagi, William [Silagi.William@epa.gov]
Subject: RE: OMB comments on IQ valuation for perchlorate rule, and OPPT's dust-lead rule
Attachments: 0203 HRRCA for the Proposed Perchlorate Rule v4.docx; Final Version for Signature NPDWR Proposed Perchlorate Rule 5-23-19.docx

Hi William,

Here is a copy of the final HRRCA as well as the Rule Preamble. I am having issues with my network folder, as soon as I resolve that issue I will send you the redline version.

Thanks
Sam

=====

Samuel Hernández Quiñones, P.E.
Environmental Engineer
Office of Water
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
202-564-1735

"USEPA Protecting Human Health and the Environment"

From: Silagi, William
Sent: Thursday, June 13, 2019 9:38 AM
To: Hernandez-Quinones, Samuel <Hernandez.Samuel@epa.gov>; Khera, Rajiv <Khera.Rajiv@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Dockins, Chris <Dockins.Chris@epa.gov>; Klemick, Heather <Klemick.Heather@epa.gov>; Helm, Erik <Helm.Erik@epa.gov>; Wolverton, Ann <Wolverton.Ann@epa.gov>
Subject: OMB comments on IQ valuation for perchlorate rule, and OPPT's dust-lead rule

Sam, Rajiv and Eric,

OPPT is trying to wrap up interagency review for our dust-lead hazard standards rule. The economic analysis for this rule uses the same IQ valuation methodology that OW used for the perchlorate rule analysis. We've received a number of comments from OMB on the IQ methodology (attached). I understand that you received many of the exact same comments.

Could you send us a copy of your written responses to OMB?

While we have our own thoughts about answers to these questions, we wouldn't want to say anything that might be perceived as being inconsistent with responses the Agency has already provided.

We are trying to respond to OMB tomorrow (so that the rule can be cleared by OMB next week), so it would be helpful if you could provide copies of your responses today.

Thanks.

William Silagi
Economic and Policy Analysis Branch
U.S. EPA Office of Pollution Prevention and Toxics
Mail Code 7406M, 1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: (202) 564-8788
silagi.william@epa.gov

From: Dockins, Chris
Sent: Thursday, June 13, 2019 8:41 AM
To: Silagi, William <Silagi.William@epa.gov>; Klemick, Heather <Klemick.Heather@epa.gov>
Cc: Helm, Erik <Helm.Erik@epa.gov>; Wolverton, Ann <Wolverton.Ann@epa.gov>
Subject: RE: OMB comments on IQ valuation -- dust lead: perchlorate

Hi Bill --

I received a review draft of the EA from Sam Hernandez-Quinones originally, and then a copy with some OMB comments in early May via others in OP. And Heather sent that language on monetizing IQ benefits to Rajiv Khera in early May. I know OP senior management was involved with the negotiations with OMB, but I have not seen the questions, responses, or an EA since May 2.

I've been looking for the final EA on regulations.gov since EPA announced the proposal, but it doesn't appear to be there.

I really wish I had more information. Sam, Rajiv, Erik, and/or maybe Eric Burneson will need to help us out more on the OMB interactions and documents.

- C

From: Silagi, William
Sent: Thursday, June 13, 2019 8:13 AM
To: Klemick, Heather <Klemick.Heather@epa.gov>; Dockins, Chris <Dockins.Chris@epa.gov>
Cc: Helm, Erik <Helm.Erik@epa.gov>; Wolverton, Ann <Wolverton.Ann@epa.gov>
Subject: OMB comments on IQ valuation -- dust lead: perchlorate

We've received comments from OMB on the dust-lead rule that focus on the IQ valuation. I understand that many of these are repeats of comments that OMB made on the perchlorate rule analysis. Does anyone have copies of the Agency's responses to those questions? I don't know that we'd want to repeat those responses (since those didn't seem to have cleared things up for OMB), but it would be helpful to be aware of what we already said.

Chris, who is the appropriate contact is for the perchlorate rule analysis?

Message

From: Mejias, Melissa [mejias.melissa@epa.gov]
Sent: 4/11/2019 8:58:37 PM
To: Ross, David P [ross.davidp@epa.gov]
Subject: FW: Perchlorate
Attachments: Perchlorate Proposed NPDWR Redline 4-5-19.2.pdf

.pdf version

From: Jones, Lindsey
Sent: Thursday, April 11, 2019 4:54 PM
To: Forsgren, Lee <Forsgren.Lee@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Mejias, Melissa <mejias.melissa@epa.gov>
Cc: Ross, David P <ross.davidp@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>
Subject: RE: Perchlorate

Hi Lee,

I provided some additional comments on Nancy's draft. Could you also tell me where this is in the review process? Is this the latest version or will we be getting another?

Thank you,
Lindsey

From: Forsgren, Lee
Sent: Wednesday, April 10, 2019 1:19 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>; Mejias, Melissa <mejias.melissa@epa.gov>
Cc: Jones, Lindsey <jones.lindsey@epa.gov>; Ross, David P <ross.davidp@epa.gov>
Subject: RE: Perchlorate

Nancy,

Appreciate that there isn't much time to review but we are facing a very tight court ordered timeline to publish a proposed MCLG. That deadline is May 28th and the Administrator is facing a contempt of court citation if we fail to meet that deadline. As you might guess his direction has been clear that we will not put him in a circumstance where he is in contempt of court.

We will certainly add text to clarify the uncertainties and shortcomings of some of the literature in the areas that you identified and incorporate a reference to the agency's data derived extrapolation factors. We did discuss it in the context of cost benefit but can certainly address them in the context of the MCLG.

Ex. 5 Deliberative Process (DP)

If you have any other questions please let me know.

Regards,
Lee

D. Lee Forsgren

Deputy Assistant Administrator
Office of Water
Environmental Protection Agency
1200 Pennsylvania, Avenue NW
Room 3219B WJC East Building
Washington, DC 20460
202-564-5700

From: Beck, Nancy
Sent: Wednesday, April 10, 2019 11:37 AM
To: Mejias, Melissa <mejias.melissa@epa.gov>
Cc: Forsgren, Lee <Forsgren.Lee@epa.gov>; Jones, Lindsey <jones.lindsey@epa.gov>
Subject: RE: Perchlorate

Melissa and Lee,

Thanks for the opportunity to review. I am hugely swamped trying to get 2 of our rules and 2 risk evaluations over to OMB so I could only review very quickly.

I looked back at some of our previous comments and flagged a few that I don't think were addressed. I also notice that your team did address many of our previous comments—thank you for that!

I also flagged the new IQ section—It gives me some heartburn based on where the Administrator wanted us to go in our lead rules, so I flagged that for you.

Lindsay may have additional thoughts/more time to review.

Thanks again,
Nancy

Nancy B. Beck, Ph.D., DABT
Principal Deputy Assistant Administrator, OCSP
P: 202-564-1273
beck.nancy@epa.gov

From: Mejias, Melissa
Sent: Tuesday, April 9, 2019 10:39 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Forsgren, Lee <Forsgren.Lee@epa.gov>
Subject: Perchlorate